"A COMPARATIVE STUDY OF GUM ELASTIC BOUGIE GUIDED INSERTION OF PROSEAL LARYNGEAL MASK AIRWAY WITH DIGITAL TECHNIQUE IN ANAESTHETIZED SPONTANEOUSLY BREATHING PATIENTS UNDERGOING ELECTIVE MINOR GYNAECOLOGICAL SURGERIES"

Dissertation submitted to

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

In partial fulfillment for the award of the degree of

DOCTOR OF MEDICINE

IN

ANAESTHESIOLOGY

BRANCH X

INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE
MADRAS MEDICAL COLLEGE
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APRIL 2016

CERTIFICATE OF THE GUIDE

This is to certify that the dissertation titled, "**A comparative study of gum elastic bougie guided insertion of Proseal laryngeal mask airway with digital technique in anaesthetized spontaneously breathing patients undergoing elective minor gynaecological surgeries"** submitted by **Dr. JOONA. P** in partial fulfillment for the award of the degree of DOCTOR OF MEDICINE in Anaesthesiology by The Tamilnadu Dr. M.G.R. Medical University, Chennai is a bonafide record of work done by her in the INSTITUTE OF OBSTETRICS AND GYNAECOLOGY, Madras Medical College and Rajiv Gandhi Govt. General Hospital, during the academic year 2013 -2016**.**

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Place:

CERTIFICATE

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DECLARATION

I, **Dr.JOONA P** hereby declare that the dissertation titled, "**A comparative study of gum elastic bougie guided insertion of Proseal laryngeal mask airway with digital technique in anaesthetized spontaneously breathing patients undergoing elective minor gynaecological surgeries"** has been prepared by me under the guidance of **Prof. Dr. B. CHANDRIKA. M.D., D.A.,** Professor of Anaesthesiology, Institute of Obstetrics and Gynaecology, Madras Medical college and Rajiv Gandhi Govt. General Hospital, Chennai, in partial fulfillment of the regulations for the award of the degree of M.D (Anaesthesiology) examination to be held in April 2016.

This study was conducted at Institute of Obstetrics and Gynaecology, Madras Medical College and Rajiv Gandhi Govt. General Hospital, Chennai.

I have not submitted this dissertation previously to any journal or any university for the award of any degree or diploma.

Date:

Place: Chennai

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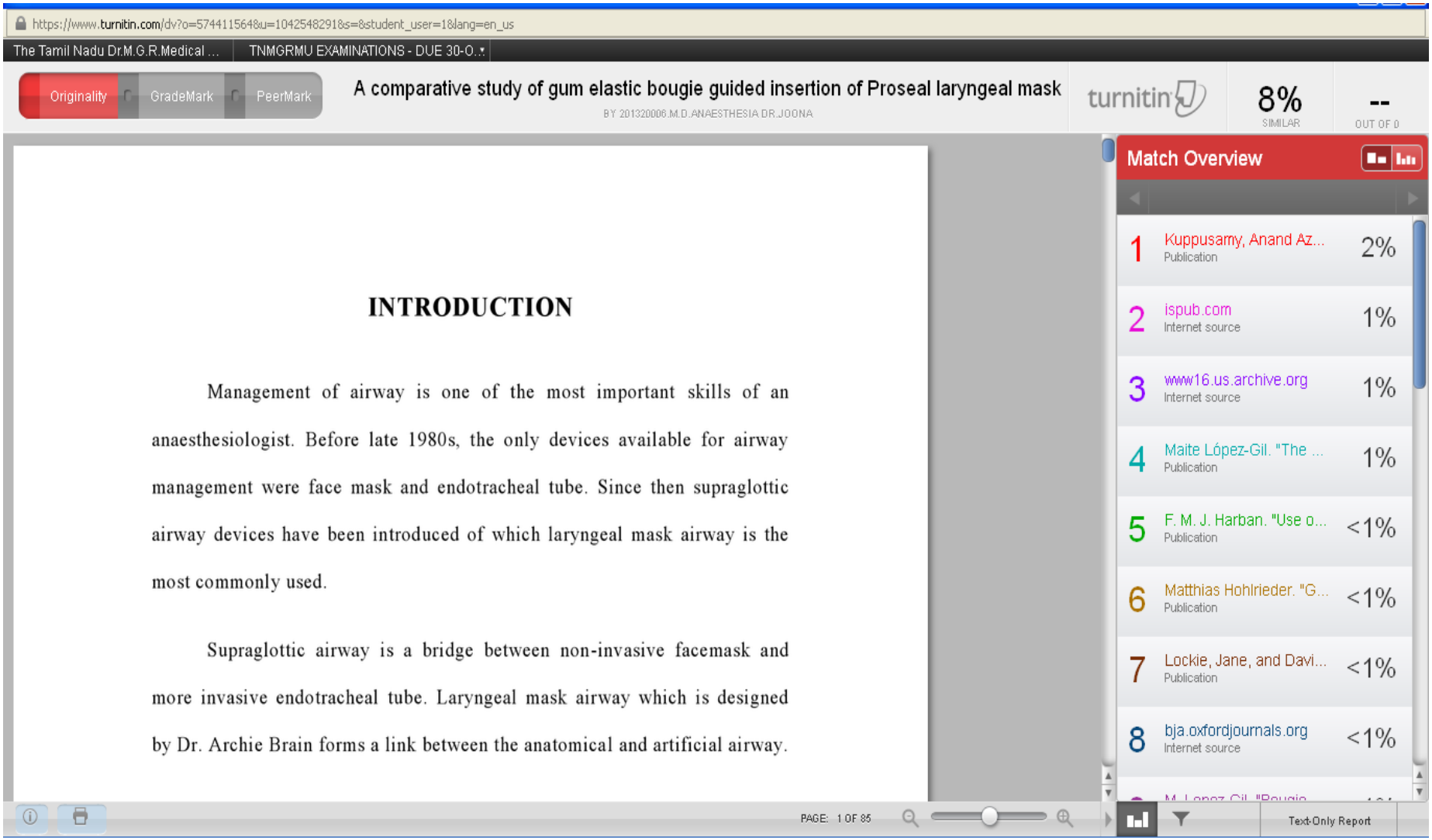
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INTRODUCTION
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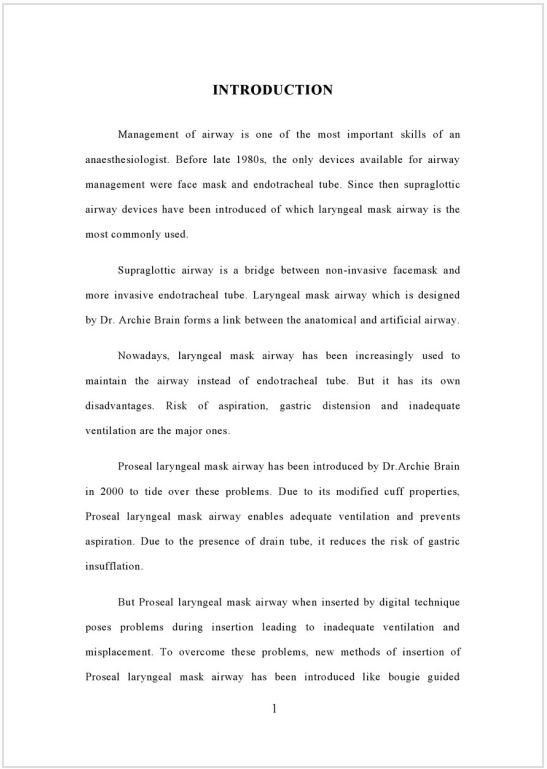

INTRODUCTION

Management of airway is one of the most important skills of an anaesthesiologist. Before late 1980s, the only devices available for airway management were face mask and endotracheal tube. Since then supraglottic airway devices have been introduced of which laryngeal mask airway is the most commonly used.

Supraglottic airway is a bridge between non-invasive facemask and more invasive endotracheal tube. Laryngeal mask airway which is designed by Dr. Archie Brain forms a link between the anatomical and artificial airway.

Nowadays, laryngeal mask airway has been increasingly used to maintain the airway instead of endotracheal tube. But it has its own disadvantages. Risk of aspiration, gastric distension and inadequate ventilation are the major ones.

Proseal laryngeal mask airway has been introduced by Dr.Archie Brain in 2000 to tide over these problems. Due to its modified cuff properties, Proseal laryngeal mask airway enables adequate ventilation and prevents aspiration. Due to the presence of drain tube, it reduces the risk of gastric insufflation.

But Proseal laryngeal mask airway when inserted by digital technique poses problems during insertion leading to inadequate ventilation and misplacement. To overcome these problems, new methods of insertion of Proseal laryngeal mask airway has been introduced like bougie guided

1

ABBREVIATIONS

ASA-PS	:	American Society of Anaesthesiologists Physical Status
GEB	:	Gum Elastic Bougie
PLMA	:	Proseal Laryngeal Mask Airway
$ETCO_2$	:	End Tidal Carbon Dioxide
AL- OP	:	Air Leak Oropharynx
AL- G	:	Air Leak Gastric
AL- DT	:	Air Leak Drain Tube
FPP	:	Failed Passage into Pharynx
SSN TT	:	Suprasternal Notch Tap Test
IV	:	Ineffective Ventilation
OLP	:	Oropharyngeal Leak Pressure
HR	:	Heart Rate
SBP	:	Systolic Blood Pressure
DBP	:	Diastolic Blood Pressure
MAP	:	Mean Arterial Pressure

ABSTRACT

Introduction: Supraglottic airway device is a bridge between non-invasive facemask and more invasive endotracheal tube. Laryngeal mask airway has the risk of aspiration, gastric insufflation and inadequate ventilation. Proseal laryngeal mask airway is a specialized form of laryngeal mask airway which due to its large ventral cuff and presence of dorsal cuff enables adequate ventilation and prevents aspiration. Due to the presence of drain tube, it reduces the risk of gastric insufflation.

But Proseal laryngeal mask airway when inserted by classical digital technique poses problems during insertion leading to inadequate ventilation and misplacement. To overcome these problems, new methods of insertion like bougie guided technique and introducer tool technique have been introduced.

Aim: We compared the classical digital technique with gum elastic bougie guided technique for insertion of Proseal laryngeal mask airway with respect to number of attempts to successful placement, effective airway time, hemodynamic response to insertion, airway trauma during insertion, presence of visible blood staining and post-operative airway morbidity.

Methods: After obtaining written informed consent from the patients and clearance from the Institutional Ethics Committee, the study was conducted in minor gynaecological operation theatre, Institute of Obstetrics and Gynaecology, Egmore. The study was carried out in sixty anaesthetized spontaneously breathing female patients in the age group of 21-60 years belonging to American Society of Anaesthesiologists Physical Status 1&2 posted for elective minor gynaecological surgeries at the Institute of Obstetrics and Gynaecology, Egmore. Proseal laryngeal mask airway was inserted by index finger technique in the digital group. Gum elastic

bougie guided technique involved priming the drain tube of Proseal laryngeal mask airway with gum elastic bougie and inserting the bougie into the esophagus with the help of a laryngoscope followed by railroading the Proseal laryngeal mask airway over the bougie.

Results: Number of attempts to successful insertion, airway trauma during insertion, presence of visible blood staining and hemodynamic response to insertion were comparable among the two study groups. Effective airway time and oropharyngeal leak pressure were significantly higher for gum elastic bougie guided technique when compared to digital technique. Sore throat was the most common post-operative airway morbidity in digital technique group while dysphagia was more common in patients belonging to gum elastic bougie guided group.

Conclusion: The gum elastic bougie guided insertion of Proseal laryngeal mask airway is an excellent alternative to classical digital technique in adults with regard to number of attempts to successful placement, hemodynamic response to insertion, airway trauma during insertion and presence of visible blood staining. High oropharyngeal leak pressure associated with gum elastic bougie guided insertion makes it a more effective alternative to classical digital technique.

Key words: Laryngeal mask airway, Proseal, insertion, gum elastic bougie, technique

INTRODUCTION

Management of airway is one of the most important skills of an anaesthesiologist. Before late 1980s, the devices available for airway management were face mask and endotracheal tube only. Since then supraglottic airway devices have been introduced of which laryngeal mask airway is the most commonly used.

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But Proseal laryngeal mask airway when inserted by digital technique poses problems during insertion leading to inadequate ventilation and misplacement. To overcome these problems, new methods of insertion of Proseal laryngeal mask airway has been introduced like bougie guided

technique and introducer tool technique. These new techniques help in better and easier insertion of Proseal laryngeal mask airway.

My study compares the classical digital technique with gum elastic bougie guided technique for insertion of Proseal laryngeal mask airway.

AIM OF THE STUDY

My study aims to compare gum elastic bougie guided insertion of Proseal laryngeal mask airway with digital technique in adults with respect to

1) Number of attempts to successful placement

2) Effective airway time

3) Hemodynamic response to insertion

4) Airway trauma during insertion

5) Presence of visible blood staining

6) Post-operative airway morbidity

ANATOMY OF AIRWAY

A thorough understanding of the anatomy of airway especially that of the pharynx and larynx is inevitable for successful airway management with supraglottic airway devices like Proseal laryngeal mask airway.

The airway is divided into upper and lower airway. Upper airway includes nasal cavity, oral cavity, pharynx and larynx. Lower airway includes the tracheobronchial tree.

The airway begins at the nares which forms the external opening of the nasal cavity. The septum of nose divides the nasal cavity into two halves. Nasal septum is formed by quadrilateral cartilage anteriorly and vomer and ethmoid posteriorly. The lateral wall of nose has three bony projections called turbinates. The space under each turbinate is known as meatus.

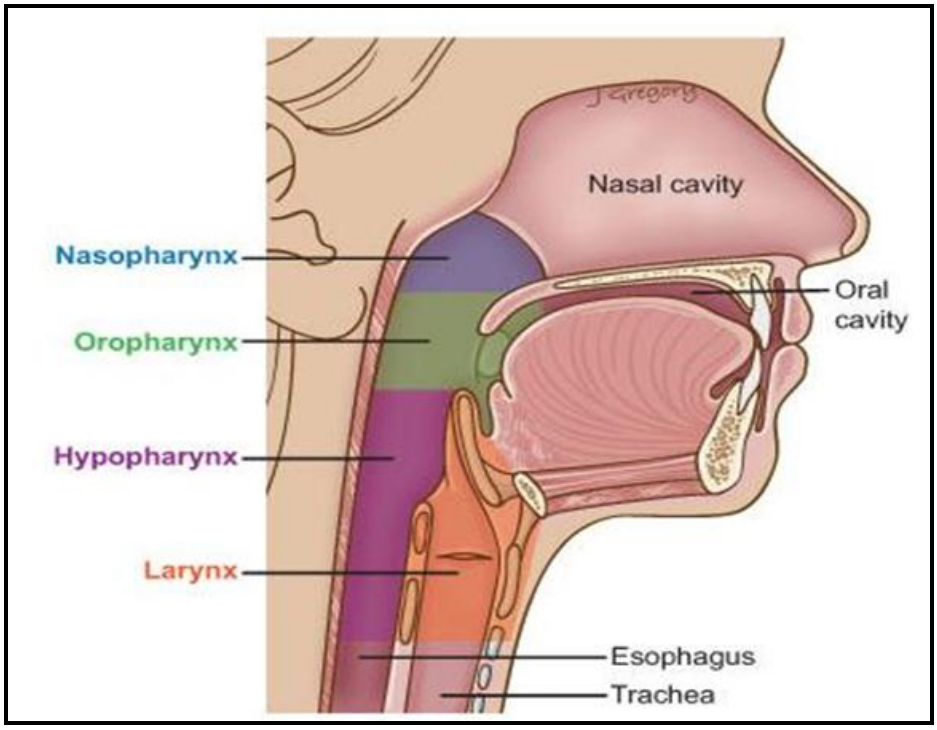
Due to high risk of trauma and small size of nasal cavity, oral cavity is commonly used as the conduit for airway devices. Oral cavity extends from the lips to the anterior tonsillar pillar. It consists of lips, buccal mucosa, gums, retromolar trigone, hard palate, tongue and floor of mouth.

Pharynx[31] is a fibromuscular tube which forms the upper part of air and food passages. It extends from the base of skull to the lower border of cricoid cartilage. Pharynx is divided into

1) Nasopharynx

2) Oropharynx

3) Laryngopharynx



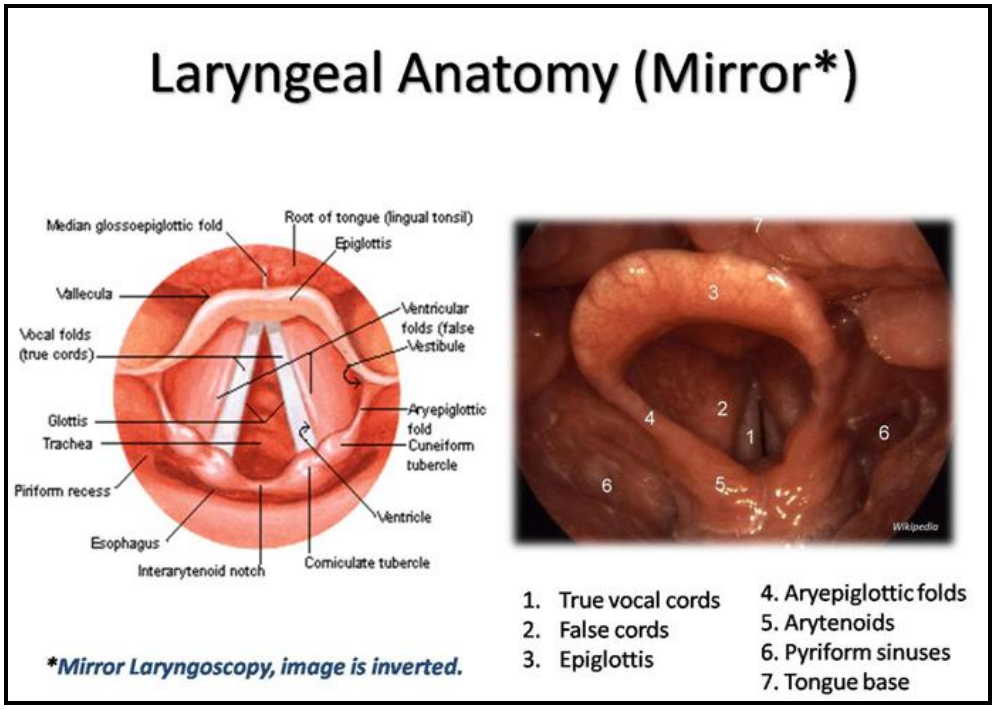
Nasopharynx or epipharynx is the uppermost part of pharynx. It is bounded superiorly by the basisphenoid and basiocciput and posteriorly by the arch of atlas and the prevertebral muscle and fascia covering it. The floor is formed by soft palate anteriorly and is deficient posteriorly. Through this posterior defect, nasopharynx communicates with oropharynx. Anterior wall is formed by choanae. Choanae of both sides are separated from each other by the posterior border of septum of nose. Lateral wall contains pharyngeal opening of Eustachian tube, torus tubarius and fossa of Rosenmuller.

Oropharynx lies behind the oral cavity and is separated from the oral cavity by oropharyngeal isthmus. The anterior boundary is formed by the base of tongue, lingual tonsils and valleculae. Lateral wall contains palatine tonsils and anterior and posterior tonsillar pillars. Posterior wall is formed by second and third cervical vertebrae.

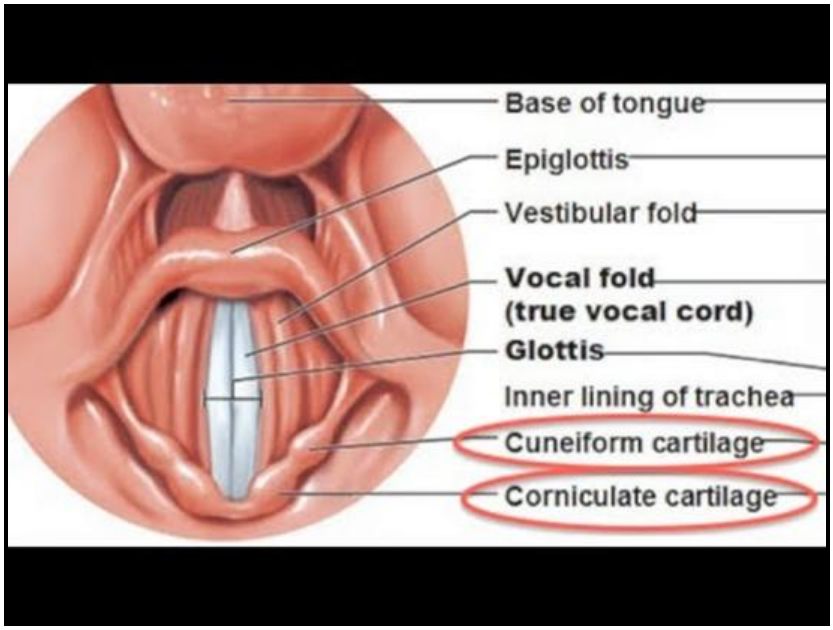
Laryngopharynx or hypopharynx is the lowermost part of the pharynx. It lies posterior and lateral to larynx and extends from the hyoid bone to the lower border of cricoid cartilage. It is clinically divided into postcricoid region, pyriform fossa and posterior pharyngeal wall.

Larynx acts as the inlet to trachea and functions as the organ of phonation and airway protection. It lies opposite to third to sixth cervical vertebrae and lies anterior to hypopharynx. It consists of muscles, ligaments and cartilages. There are nine cartilages including three unpaired [thyroid, cricoid and epiglottis] and three paired [corniculate, cuneiform and arytenoid] cartilages. They are joined together by membranes, ligaments and synovial joints. Thyroid cartilage is the largest among these cartilages. The superior thyroid notch and the corresponding laryngeal prominence [Adam's apple] act as important anatomical landmarks for performing percutaneous airway techniques. Cricoid is the only complete cartilaginous ring in the airway and is located at the level of sixth cervical vertebra. Epiglottis is a fibrous cartilage which overhangs the laryngeal inlet and helps to divert food away from the larynx during swallowing.

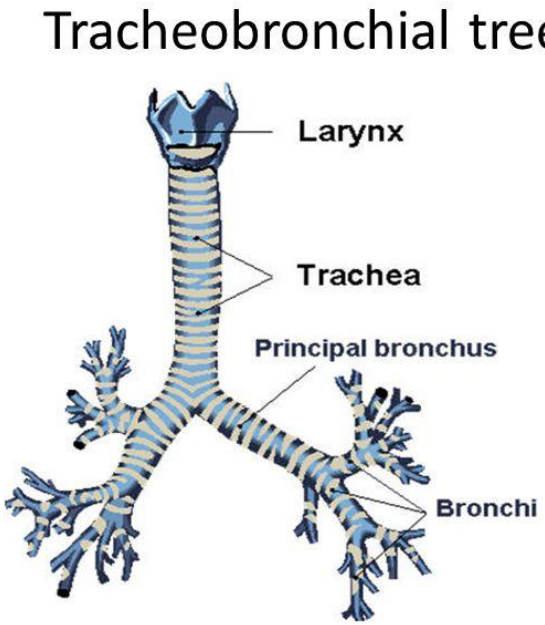
Inlet of larynx is formed by epiglottis, arytenoids and the aryepiglottic folds which connect them together. Cavity of larynx extends from epiglottis to the lower border of cricoid cartilage. Laryngeal cavity is divided into vestibule, ventricle and subglottic space by the vestibular and vocal folds. Vestibular folds extend from anterolateral part of arytenoids to the angle of thyroid where it attaches to the epiglottis. They are also known as the false vocal cords.



Vocal folds or true vocal cords extend from the angle of thyroid to arytenoids. The true vocal cords form a triangular opening called glottis. Part of the cavity of larynx above vestibular folds is called vestibule, between vestibular and vocal folds is called ventricle and part of the cavity below the vocal folds is called subglottis.



Lower airway is formed by trachea and bronchi. Trachea extends from the lower border of cricoid cartilage [at the level of sixth cervical vertebra] to the carina [at the level of fifth thoracic vertebra]. It is formed by 16-20 c-shaped rings of cartilage that are deficient posteriorly and are joined by fibrofatty tissue. At the level of carina, trachea divides into right and left main stem bronchi. Right main stem bronchus is shorter, wider and more vertical than the left main stem bronchus. Hence endotracheal tube and foreign bodies are more likely to enter into right bronchi than the left.



PROSEAL LARYNGEAL MASK AIRWAY

Proseal laryngeal mask airway is a newer supraglotic airway device designed by Dr. Archie Brain in 2000. Among the specialized laryngeal mask airway devices, it is the most complex one. The primary goal of designing such an airway device was to provide improved ventilatory characterestics and to protect against gastric insufflation and pulmonary aspiration. The special features are its modified cuff and presence of drain tube.

CONCEPT AND DESIGN[33]

Proseal laryngeal mask airway is made of medical-grade silicone. It is reusable and is latex free. It has four main parts

1) Airway tube

2) Drain tube

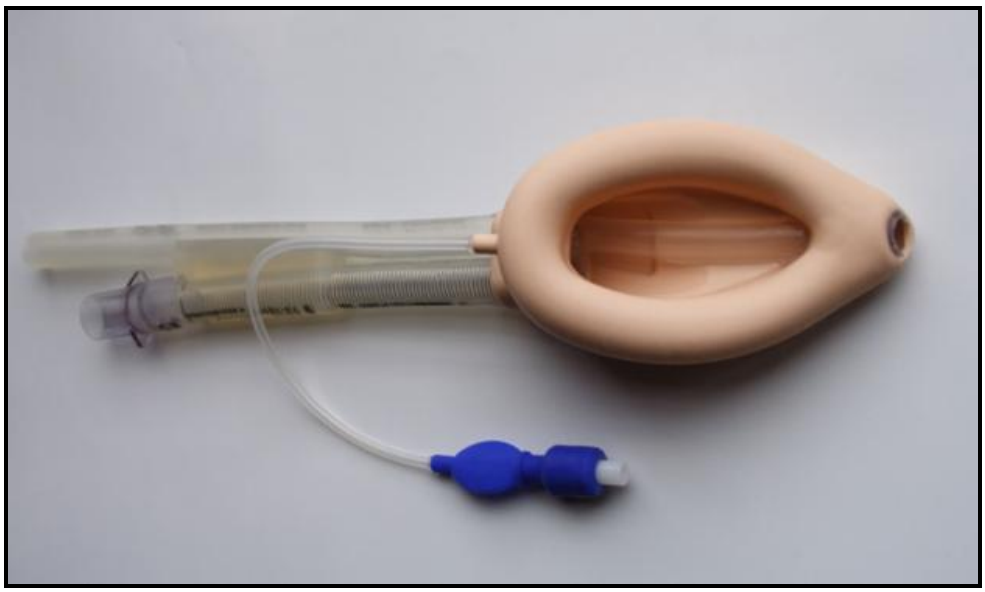
3) Mask

4) Inflation line and pilot balloon

Proseal laryngeal mask airway has a dorsal cuff which pushes the ventral cuff anteriorly and hence improves the seal. The larger proximal part of ventral cuff improves the seal by better approximation with proximal pharynx. Proseal laryngeal mask airway has a deeper bowl without aperture bars which helps to reduce the resistance to gas flow. The cuff has different dimensions among different sizes even though it has identical proportions.

Parallel double tube configuration of the Proseal laryngeal mask airway provides better stability. Airway tube is flexible and wire reinforced which prevents it from kinking.

Presence of drain tube facilitates gastric tube insertion, prevents gastric insufflation and pulmonary aspiration. There is a supporting ring at the distal end of drain tube which prevents it from collapsing when the cuff is inflated. The distal aperture of the drain tube is anteriorly sloped which provides a leading edge while inserting the Proseal laryngeal mask airway



The drain tube passes within the bowl hence acting as an aperture bar to provide accessory vent. Also there is no change in the external shape of the bowl.

Proseal laryngeal mask airway has a built-in-bite block which prevents airway obstruction and damage to the device during biting. It provides information about the depth of insertion and helps to fuse airway tube and drain tube together.

The introducer strap provides stability while inserting the Proseal laryngeal mask airway by preventing the finger from slipping off the tube.

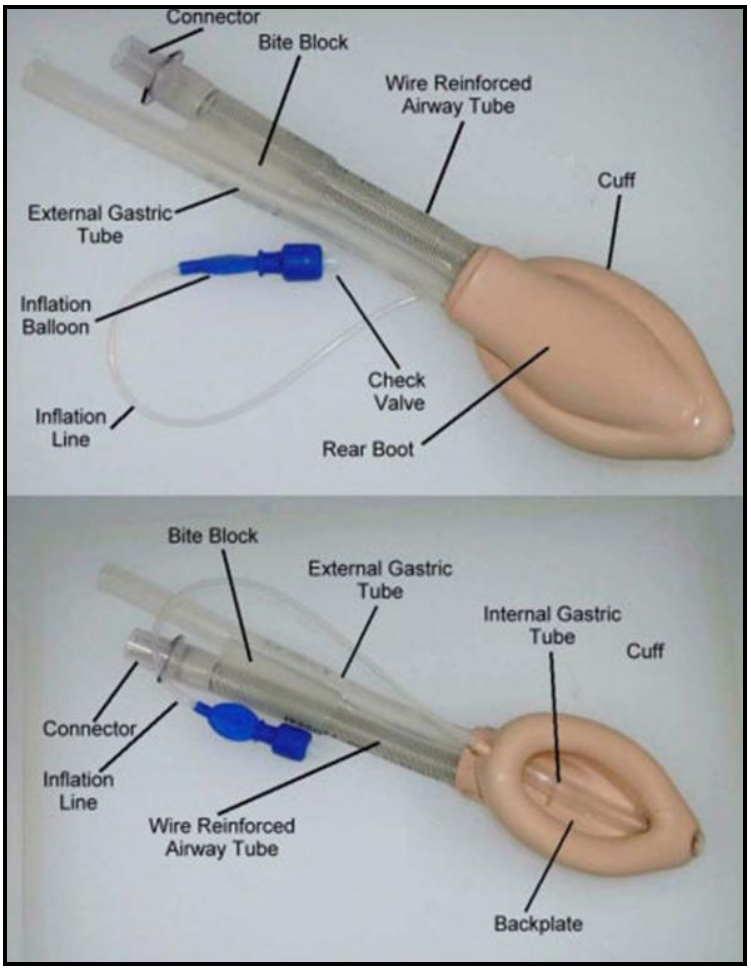
Introducer tool provided with Proseal laryngeal mask airway is a reusable device which consists of a guiding handle and a metal blade which is thin, curved and malleable. In order to reduce the risk of trauma, a thin layer of transparent silicone coating is given over the inner surface of the device and also over its curved tip. The distal end of the introducer tool fits into the locating strap. The proximal end fits over the part of airway tube above the bite block.

Cuff deflator: Cuff deflator helps in complete deflation of the cuff for successful insertion, proper positioning and sterilization of Proseal laryngeal mask airway.

Size selection: Size of Proseal laryngeal mask airway is selected according to the weight of the patient. It is available in six sizes.

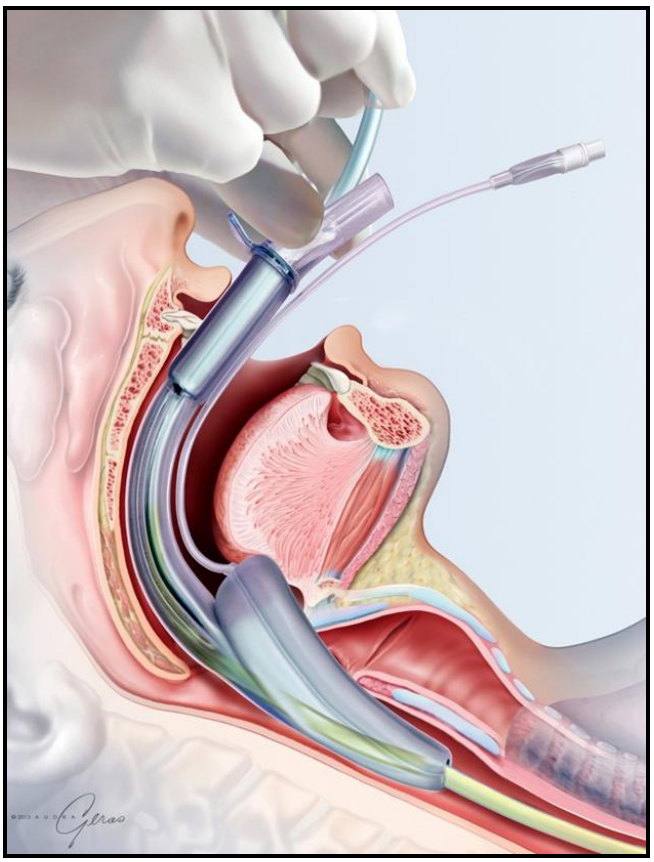
LMA-ProSeal

LMA Size	*Weight (kg)*	*Max Cuff Inflation Volume (mL)*	*Max. Fiberoptic Scope Size (mm)*	*Max. gastric Tube Size (Fr)*	*Length of Drain Tube (cm)*	*Largest Tracheal Tube (ID in mm)*
1.5	5 to 10	7	-	10	18.2	4.0 uncuffed
2	10 to 20	10	-	10	19.0	4.0 uncuffed
2.5	20 to 30	14	-	14	23.0	4.5 uncuffed
3	30 to 50	20	-	16	26.5	5.0 uncuffed
4	50 to 70	30	4	16	27.5	5.0 uncuffed
5	70 to 100	40	5	18	28.5	6.0 cuffed

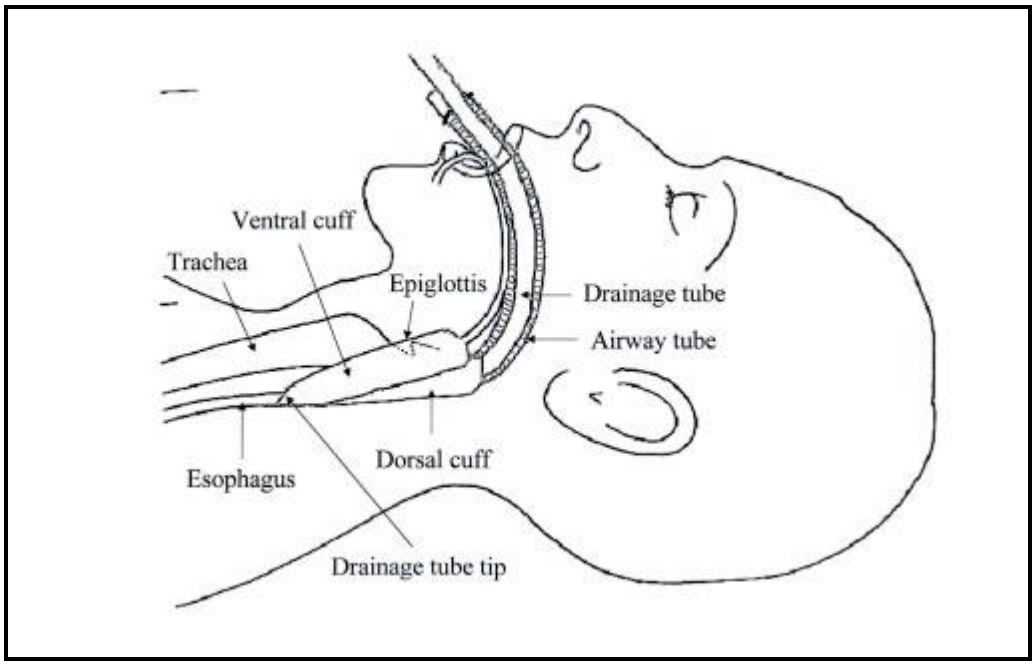


ANATOMICAL ORIENTATION OF PROSEAL LARYNGEAL MASK AIRWAY AFTER INSERTION[13]

Proseal laryngeal mask airway provides a proper seal around the respiratory and gastrointestinal tract apart from providing a conduit to both tracts. The distal cuff which is larger and conical in shape fills the hypo-pharynx more completely. Wedge shaped proximal cuff fills the proximal part of laryngopharynx both forming a proper seal with their respective tracts. Ventral cuff is pressed more firmly against the periglottic tissues by the dorsal cuff. Because of the narrow diameter and parallel arrangement of the tubes, proximal cuff is more effectively covered by the base of tongue thereby forming a more effective plug in the proximal pharynx.



On insertion, the cuff of Proseal laryngeal mask airway is pressed against hard palate, soft palate, nasopharyngeal, oropharyngeal and hypopharyngeal portions of posterior pharyngeal wall. When Proseal laryngeal mask airway is optimally placed, the distal cuff lies in the hypo-pharynx at the junction of upper respiratory and gastrointestinal tracts forming a low pressure seal around the glottis. The upper part of the mask lies below the base of tongue and epiglottis rests within the bowl of the mask. When inflated, the tip of the mask lies against the upper esophageal sphincter behind the cricoid cartilage and the sides face towards the pyriform fossa.



PREPARATION FOR USE

With proper maintenance Proseal laryngeal mask airway can be used around 40 times.

CLEANING: Proseal laryngeal mask airway is thoroughly cleaned until all the visible foreign matter is removed. The cleaning solution used is warm water and dilute sodium bicarbonate. Airway tube and drain tube are cleaned by rinsing in warm flowing water. The inside of airway tube and drain tube is cleaned with the help of a soft bristle brush.

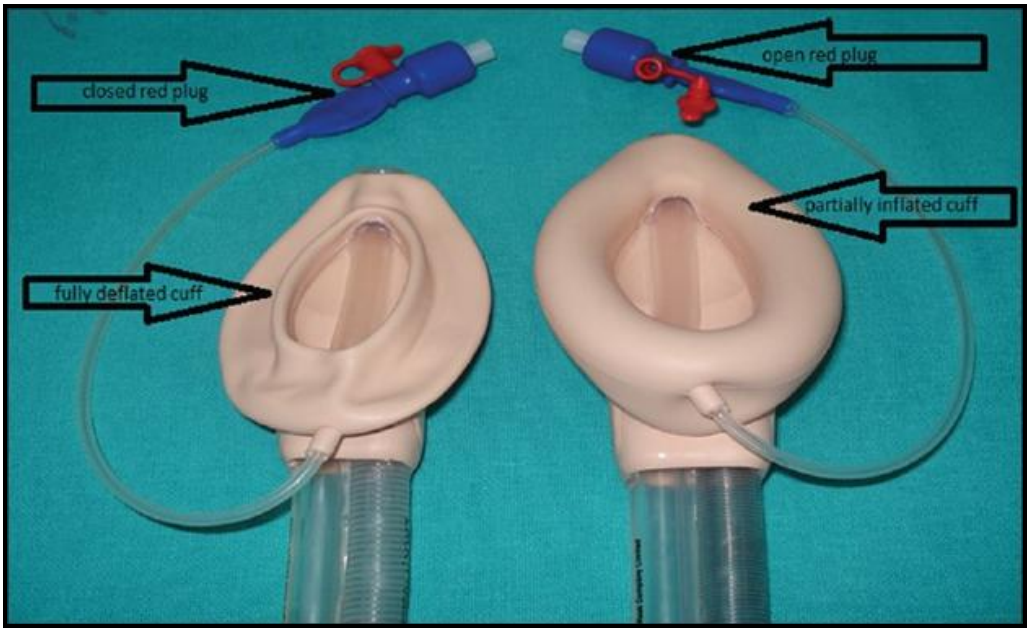
STERILIZATION: The recommended method for sterilization of Proseal laryngeal mask airway is steam autoclaving. It should be ensured that red plug is open before autoclaving so that air if present in the cuff escapes and prevents rupture.

PERFORMANCE TESTS[33]:

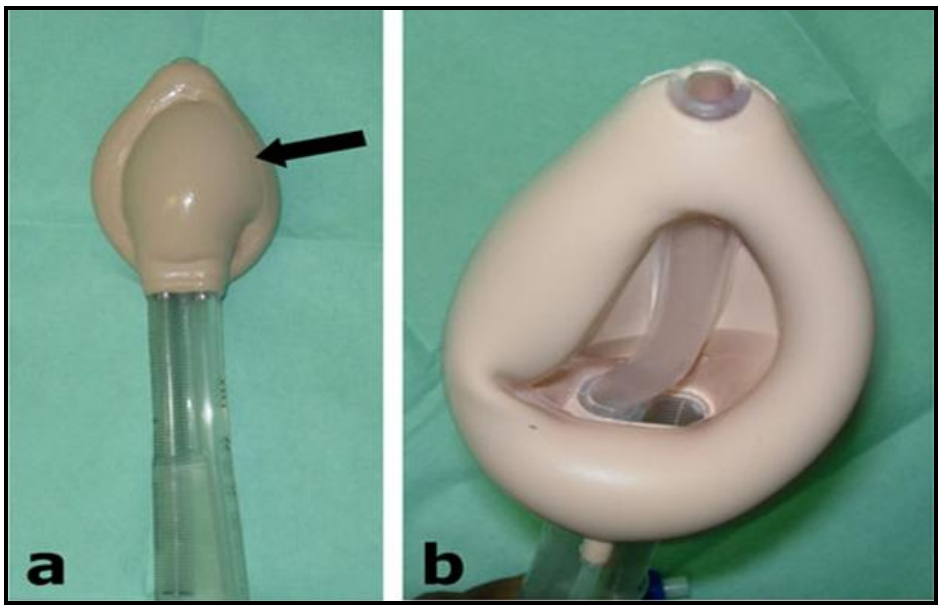
1. **Visual inspection**: The surface of Proseal laryngeal mask airway is examined for any tears or cuts. It is ensured that the tube is transparent because as we use the device the tube will gradually lose its transparency. Any damage of the part of the drain tube lying within the mask is ruled out. There should not be any foreign matter between the mask and the drain tube.

2. **Inflation and deflation**: Red plug should be closed while performing these tests.

Deflation: Deflate the laryngeal mask airway using a syringe so that walls of the cuff are tightly flattened against each other. Do not use the device if cuff walls reinflate spontaneously.



Inflation: Inflate a fully deflated cuff with 50% more air than the maximum recommended volume. Observe for two minutes and see if the cuff is getting deflated spontaneously which indicates presence of leak. Look for the symmetry of cuff walls and make sure that there is no bulging of cuff walls. Observe the inside of the drain tube where it passes through the mask and make sure that it is not collapsed.



Observe the pilot balloon when the cuff is inflated with 50% more volume of air and make sure that the pilot balloon maintains its thin slightly flattened elliptical shape.

INSERTION

Before insertion make sure that

1) Correct size of laryngeal mask airway is chosen and the device is adequately lubricated

2) Cuff wall is fully deflated and red plug is closed. The wedge shape of the deflated cuff reduces trauma during insertion and provides better positioning. Cuff can be deflated using Proseal laryngeal mask airway cuff deflator.

3) Standard monitoring parameters [ECG, NIBP, SpO_2, $ETCO_2$] are connected

4) The patient is adequately preoxygenated

5) Plane of anaesthesia adequate for insertion of the device is attained

6) Head of the patient is kept in sniffing position which is the ideal position for insertion of the device where head is extended with flexion of the neck

7) Excess force is not used for inserting the device

8) Operator stands behind the patient at the head end [exception: thumb insertion technique where operator stands in front of the patient]

INSERTION METHODS

One of the following methods can be used for insertion of Proseal laryngeal mask airway.

1) Introducer insertion technique

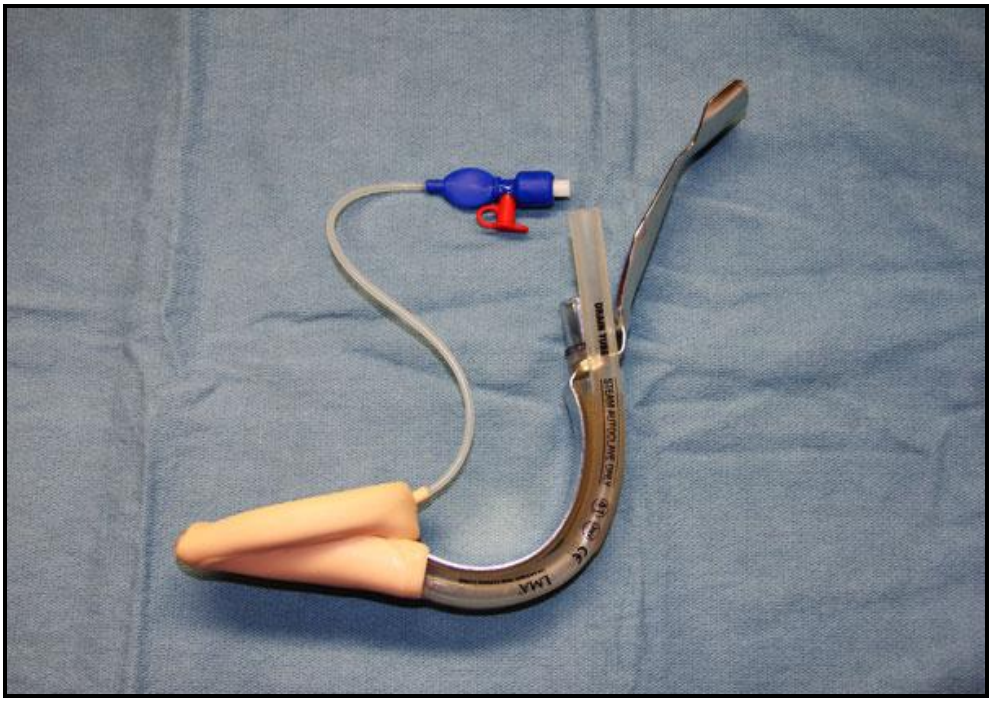
2) Index finger insertion technique

3) Thumb insertion technique

4) Gum elastic bougie guided technique

INTRODUCER INSERTION TECHNIQUE[34]

- The tip of the introducer is placed into the retaining slot
- Airway tube is folded along the convex surface of the introducer blade
- Proximal end of the airway tube is fitted into the matching slot of the introducer tool
- The cuff of Proseal laryngeal mask airway is pressed against the hard palate and the device is introduced along the curvature of hard palate
- The introducer blade is placed close to the chin and rotated inwards in a smooth circular motion.



- The device is advanced into the hypopharynx till a definite resistance is felt

- The device is held in non-dominant hand and the introducer is removed in circular motion. Stabilizing the device with non-dominant hand helps to insert the device further inwards if it is not inserted fully using the introducer tool. The Proseal laryngeal mask airway is then inflated and fixed.

INDEX FINGER INSERTION TECHNIQUE[34]

- This technique is not used for 1.5,2 and 2.5 sizes of Proseal laryngeal mask airway.

- The device is held in hand like a pen with the index finger kept in the introducer strap.

- The tip of the cuff is pressed against the hard palate and flattened against it.
- The device is introduced along the curvature of the hard palate by retaining the index finger in the introducer strap.
- The device is introduced further by flexion of wrist and extension of index finger until a definite resistance is felt.
- Before taking the index finger out of the mouth, device is pushed down by the non-dominant hand which prevents the laryngeal mask airway from getting dislodged and pulled out. It also helps to insert the device further inwards if it is not inserted fully using index finger.
- The Proseal laryngeal mask airway is then inflated and fixed

THUMB INSERTION TECHNIQUE

- This technique is not used for 1.5,2 and 2.5 sizes of Proseal laryngeal mask airway.
- It is used when a quick access to the airway is needed as during cardiopulmonary resuscitation or there is no access to the airway from behind.
- Operator stands in front of the patient
- Thumb is kept in the introducer strap.
- The tip of the cuff is pressed against the hard palate and flattened against it and is advanced along the curvature of the hard palate.

- As the device is introduced further inside, the thumb is used to extend the head.

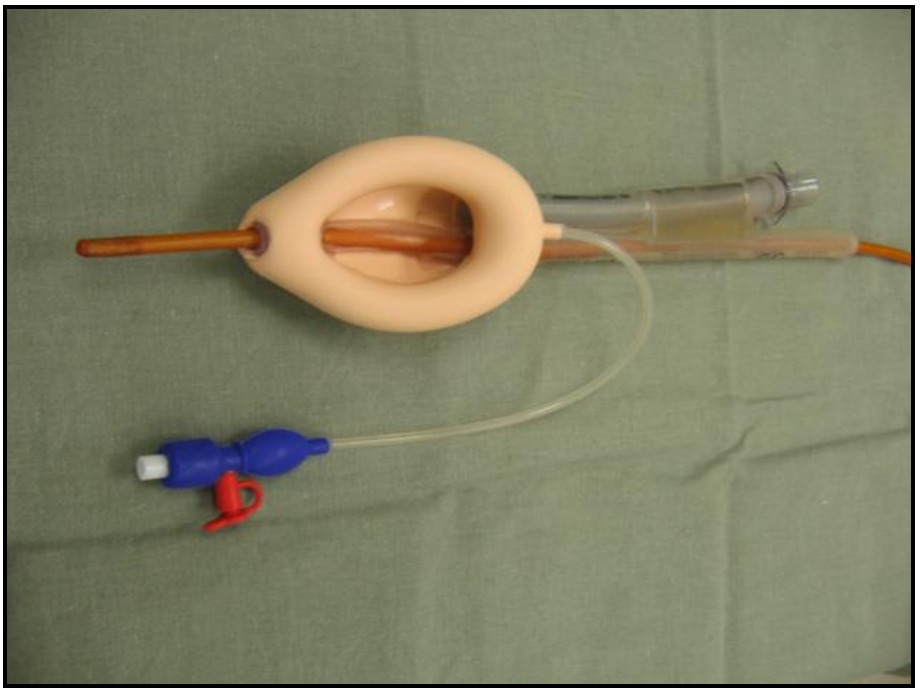
- The device is inserted until a definite resistance is felt

- Proseal laryngeal mask airway is then inflated and fixed

GUM ELASTIC BOUGIE GUIDED TECHNIQUE[19]

- Gum elastic bougie is sufficiently lubricated using a water soluble lubricant gel. Then the drain tube of Proseal laryngeal mask airway is primed with gum elastic bougie with its straight end protruding from the distal end of the drain tube leaving sufficient length of bougie at the proximal end to get a grip of it.

- By doing gentle laryngoscopy, straight end of the bougie is inserted into the esophagus.



- ❖ Laryngoscope is removed and the device is railroaded along the bougie using digital technique.

- ❖ Bougie is removed after holding the device with the non-dominant hand to prevent it from getting dislodged or pulled out.

- ❖ Alternatively, the bougie can be first placed in the esophagus and the Proseal laryngeal mask airway is then railroaded over it or the device can be railroaded over the bougie and inserted under direct vision by keeping the laryngoscope in situ.

DEVICE INFLATION

If the Proseal laryngeal mask airway is correctly positioned, the tubes will face caudally. The cuff is inflated with adequate volume of air so that intra-cuff pressure does not go beyond 60cm H_2O. Avoid holding the tube while inflating the cuff as this prevents the mask from settling into correct position. Care should be taken not to overinflate the cuff.

Signs of correct placement of Proseal laryngeal mask airway*:*

1) Slight outward movement of the tube while inflating the cuff

2) A smooth oval swelling can be seen in the neck around the area of thyroid and cricoids cartilages

3) Cuff is not visible in the oral cavity

4) Presence of chest expansion on ventilation

DEVICE FIXATION

Proseal laryngeal mask airway is fixed by putting a tape from maxilla of one side, rolling it around the device and fixing it on the maxilla of other side.

When the device is fixed, a gentle pressure is given on the proximal end of the airway tube. Proper fixation of the device is important because if the device migrates proximally, there will be air leak through the drain tube and positive pressure ventilation can not be done.

MALPOSITION

Main reasons are

1) Distal cuff in hypopharynx

2) Distal cuff entering into glottic inlet

3) Distal part of the cuff folded over

4) Severe epiglottic down folding

5) Compression of glottis

MANEUVERS FOR CORRECTING MALPOSITION

1) Distal cuff in hypopharynx: It occurs when the device is too shallow in the pharynx or when it is not fixed properly. Inserting it further inside usually corrects it.

2) If the distal cuff is in the glottis, reinsert the device.

3) Cuff folded over: This occurs when the distal part of the cuff is impinged against the posterior pharyngeal wall. It can be corrected by

   a. Inserting the device using lateral approach by introducing the cuff along the side of the hard palate

   b. Inserting the device by stiffening the drain tube using gum elastic bougie

   c. Folding is corrected by introducing a finger behind the cuff

4) Severe epiglottic down folding: This occurs when the cuff drags the epiglottis inferiorly. It can be corrected by reinserting the device by giving jaw thrust or in extreme sniffing position or by lifting the epiglottis with the help of laryngoscope.

TESTS FOR CORRECT PLACEMENT

1) Depth of insertion[26, 27]: The bite block should be at the level of teeth of the patient. Proseal laryngeal mask airway is most often malpositioned when major part of the bite block is outside the patient's mouth. The average depth of insertion of Proseal laryngeal mask airway for women is 18.6 cm and for men is 20.9 cm.

2) Test for obstructed airway: Obstruction of airway can be ruled out by

   a. Movement of chest wall with manual ventilation

   b. Square waveform of capnograph

   c. Compliance of the reservoir bag

3) Soap bubble test[29, 30]: A membrane is created over the proximal tip of the drain tube using soap solution and observed during ventilation. If the respiratory and gastrointestinal tracts are not adequately separated, the membrane will get dislodged during positive pressure ventilation.

4) Lubricant gel test: This test is also used to confirm that gastro-intestinal tract is properly separated from the airway tract so that no air leak occurs through the drain tube during positive pressure ventilation. If the lubricant gel kept on the proximal end of the drain tube gets dislodged during positive pressure ventilation, it indicates leak.

5) Suprasternal Notch Tap Test[10]: This test is used to confirm that the tip of Proseal laryngeal mask airway is placed correctly behind the cricoid cartilage. A membrane of soap solution is placed over the proximal tip of the drain tube. Pulsations of membrane on tapping the suprasternal notch confirm the position of the tip of Proseal laryngeal mask airway behind cricoid cartilage.

6) Gastric tube placement: If there is no leak in the drain tube, a gastric tube is inserted through the drain tube. Smooth passage confirms the patency of the drain tube which is important to prevent aspiration and gastric insufflation.

REASONS FOR DIFFICULTY IN INSERTING GASTRIC TUBE:

1) Selection of gastric tube with size larger than the diameter of drain tube

2) Incorrect position of Proseal laryngeal mask airway

3) Lack of adequate lubrication

4) Overinflation of Proseal laryngeal mask airway cuff

ADVANTAGES:

1) Removes gas/fluid from the stomach

2) Helps to confirm that drain tube is patent

3) In case of accidental displacement, gastric tube act as a guide for Proseal laryngeal mask airway insertion

DISADVANTAGES:

1) Risk of insertion into the trachea if Proseal laryngeal mask airway is malpositioned

2) By interfering with the function of esophageal sphincter, presence of gastric tube itself can trigger regurgitation

TESTS FOR PATENCY AND PRESENCE OF AIR LEAK

Significant air leak if present can be detected by placing the hand over drain tube and feeling for the leak or by listening over the proximal end of the drain tube. Small amount of air leak if present can be detected by performing soap bubble test.

Patency can be tested by passing a gastric tube or fiberoptic bronchoscope or by performing suprasternal notch tap test.

REVIEW OF LITERATURE

Proseal laryngeal mask airway offers distinct advantages over classic laryngeal mask airway. Modified features of cuff of Proseal laryngeal mask airway helps to provide a better seal, prevent risk of aspiration and makes it suitable for controlled ventilation. The presence of drain tube helps in easier insertion of gastric tube and decompression of stomach.

Various techniques have been described for optimal insertion of Proseal laryngeal mask airway including index finger insertion technique, thumb insertion technique, introducer tool technique and gum elastic bougie guided technique.

The literature is searched and reviewed to find out which technique of insertion of Proseal laryngeal mask airway is superior.

1] Howath.A, Brimacombe.J, Keller.C et al[19] in 2002 determined the success rate of gum elastic bougie guided insertion of Proseal laryngeal mask airway by conducting a study in 100 adult patients belonging to ASA-PS 1&2 of 18-80 years of age. Drain tube of Proseal laryngeal mask airway was primed with a 16Fr well lubricated gum elastic bougie. The straight end of the bougie was introduced into the esophagus with the help of a laryngoscope and Proseal laryngeal mask airway was railroaded over it. Ease of insertion, oropharyngeal leak pressure, ease of gastric tube placement and visible blood staining over gum elastic bougie/ Proseal laryngeal mask airway were recorded. Proseal laryngeal mask airway insertion was successful in all patients in the first attempt. There was no significant hemodynamic response

to insertion. Average oropharyngeal leak pressure was 33cm H_2O and effective ventilation was possible in all cases. Insertion of gastric tube was possible in all cases in the first attempt.

There was no visible blood staining on gum elastic bougie, but Proseal laryngeal mask airway was blood stained in 3% of cases. The incidence of sore throat, dysphagia and dysarthria were 21%, 9% and 1%.Incidence of airway complications were not significant. Hence they concluded that gum elastic bougie guided insertion of Proseal laryngeal mask airway has high success rate and is associated with minimum hemodynamic changes and low incidence of airway trauma.

2] Joseph Brimacombe, Christian Keller, Dana Vosoba Judd et al[23] in 2004 compared digital, introducer tool and gum elastic bougie guided techniques of insertion of Proseal laryngeal mask airway. They selected 240 healthy patients of 18-80 years of age. Digital and introducer tool techniques were done according to the manufacturer's instructions. Gum elastic bougie guided technique was performed by priming the drain tube with gum elastic bougie and placing the bougie into the esophagus under direct vision and then railroading the Proseal laryngeal mask airway over the bougie. Insertion was considered as a failure in cases of failed passage into the pharynx, malposition (air leak, negative suprasternal notch tap test, failed gastric tube placement) or ineffective ventilation- tidal volume<8 ml/kg, $ETCO_2$>45 mm Hg

They compared the first attempt success rate, effective airway time, trauma during insertion, visible blood staining and post operative airway morbidity. First attempt success rate was more with gum elastic bougie guided technique, but success rate after three attempts were similar. Effective airway time was similar among three groups after first attempt, but was shorter for gum elastic bougie guided technique after three attempts. Airway trauma during insertion, visible blood staining and post-operative airway morbidity were not significantly different among three groups. Hence they concluded that gum elastic bougie guided technique is more frequently successful than digital and introducer tool techniques and gum elastic bougie guided technique can be used as a backup method whenever digital or introducer tool technique fails.

3] Brimacombe.J, Keller.C et al[3] in 2004 tested the hypothesis that after failed digital insertion, gum elastic bougie guided technique was more successful than introducer tool technique for insertion of Proseal laryngeal mask airway. They conducted the study in 100 anaesthetized patients belonging to ASA-PS 1&2 of 18 to 80 years of age in whom initial attempt to insert Proseal laryngeal mask airway using digital technique had failed. They randomly divided the patients into two groups. Gum elastic bougie guided insertion was done after priming the drain tube of Proseal laryngeal mask airway with gum elastic bougie, inserting the bougie into the esophagus with the help of laryngoscope and railroading the Proseal laryngeal mask airway along the bougie. Then the bougie was removed. Introducer technique involved attaching the introducer tool on Proseal Laryngeal mask airway,

insertion using single-handed rotation along the curvature of palate followed by removing the introducer tool. Insertion was considered as a failure in cases of failed passage into the pharynx, malposition and ineffective ventilation.

Presence of blood staining on Proseal laryngeal mask airway was documented. Gum elastic bougie guided insertion was faster and had a higher success rate compared to the introducer tool technique. Gum elastic bougie guided technique was successful in all the patients who had failed insertion using introducer tool technique. No blood staining was noted over gum elastic bougie, laryngoscope and introducer tool. But blood staining of Proseal laryngeal mask airway was more with introducer tool technique when compared to gum elastic bougie guided technique. Hence they concluded that in cases of failed digital insertion of Proseal laryngeal mask airway, gum elastic bougie guided technique is more successful and less traumatic than introducer tool technique.

4] Garcia Aguado. R, Violes. J, Brimacombe.J et al[17] in 2006 conducted a study in which they compared suction catheter guided insertion of Proseal laryngeal mask airway with digital technique. Two hundred and forty patients belonging to ASA-PS 1&2 of 18-84 years of age were randomly allotted into two groups. Digital insertion was performed according to the manufacturer's instructions. Suction catheter guided insertion involved priming the drain tube of Proseal laryngeal mask airway with suction catheter so that distal end of the catheter protrudes 15cm from the drain tube and introducing the catheter blindly into the pharynx to a depth of 15cm. The Proseal laryngeal mask airway is then railroaded over the catheter and

catheter is removed. Number of attempts to successful insertion was less for suction catheter guided technique but the overall success rates were similar. Effective airway time was shorter and lateral approach was required less frequently for suction catheter guided insertion. Trauma to mouth was more for digital insertion but overall trauma was comparable. Blood staining over the device and post-operative airway morbidity were also comparable. Hence they concluded that suction catheter guided insertion is more successful and is associated with less trauma to mouth when compared to digital technique for insertion of Proseal laryngeal mask airway.

5] M. Lopez Gil, J. Brimacombe, L. Barragan, C. Keller et al[24] in 2006 tested the hypothesis that bougie guided insertion of Proseal laryngeal mask airway is more successful than digital technique in children. They randomly allocated one hundred and twenty children belonging to ASA-PS 1&2 aged 1-16 years into two groups [digital and bougie guided insertion of Proseal laryngeal mask airway]. Digital technique was performed according to the manufacturer's instructions. In bougie guided technique, drain tube was primed with a bougie and bougie was inserted into the esophagus under direct vision. Then Proseal laryngeal mask airway was railroaded over the bougie. They compared number of attempts to successful placement, effective airway time, efficacy of seal, ease of gastric tube placement, hemodynamic response, visible blood staining and post-operative airway morbidity. The first attempt success rate was higher for bougie guided technique, but effective airway time was longer. There was no statistically significant difference in the efficacy of seal, ease of gastric tube placement, hemodynamic response to insertion, visible blood staining and post-operative airway morbidity. Hence

they concluded that bougie guided insertion of Proseal laryngeal mask airway has higher first attempt success rate than digital technique in children.

6] Sinha.A,Sharma.B and Sood.J et al[37] in 2007 studied the efficacy of Proseal laryngeal mask airway when compared to endotracheal tube in pediatric laparoscopic surgeries.60 children belonging to ASA-PS 1&2 of 6months-8yrs of age posted for elective laparoscopic surgeries were randomly allotted into two groups of 30 each. After anaesthetizing the children, Proseal laryngeal mask airway and endotracheal tube were inserted. Hemodynamic parameters, peak inspiratory pressure and $ETCO_2$ were noted. There was no statistically significant difference between the variables. Hence it was concluded that pediatric Proseal laryngeal mask airway and endotracheal tube has comparable ventilatory efficacy for elective short laparoscopic procedures.

7] Teoh.C.Y, Lim.F.S et al[40] in 2008 conducted a study in which gum elastic bougie guided technique and introducer tool technique of Proseal laryngeal mask airway insertion were compared. 124 children of 1-12 years of age belonging to ASA-PS 1&2 weighing 8-29kg undergoing peripheral surgeries were randomly divided into two groups. Gum elastic bougie guided technique involved priming the drain tube of Proseal laryngeal mask airway with gum elastic bougie, inserting the bougie into the esophagus with the help of a laryngoscope and railroading the Proseal laryngeal mask airway over the bougie followed by bougie removal. Introducer tool technique involved inserting the Proseal laryngeal mask airway with the help of introducer tool according to manufacturer's instructions. They compared rate of successful

insertion, presence of air leak through oral, gastric or drain tube, ease of gastric tube insertion and incidence of post-operative airway related complications. Gum elastic bougie group had a better efficacy of seal than introducer tool group. Other results were comparable in both groups. Hence they concluded that both gum elastic bougie guided technique and introducer tool technique were comparable for Proseal laryngeal mask airway insertion in children. When introducer tool technique fails, gum elastic bougie guided technique can be used as a backup.

8] Stephen Eschertzhuber, Joseph Brimacombe, Matthias Hohlrieder, Karl-Heinz Stadlbauer, Christian Keller et al[35] in 2008 compared guided insertion of Proseal laryngeal mask airway with digital and introducer tool techniques in patients with simulated difficult laryngoscopy using a rigid neck collar. They allocated 99 anaesthetised healthy female patients between 19-68 years of age for Proseal laryngeal mask airway insertion. Difficult laryngoscopy was simulated using a rigid neck collar. Introducer tool and digital techniques were performed according to the manufacturer's instructions. Guided technique involved priming the drain tube of Proseal laryngeal mask airway with Eschmann tracheal tube introducer, inserting the introducer under direct vision into the esophagus followed by railroading the Proseal laryngeal mask airway over it. . Insertion was considered as a failure in cases of failed passage into the pharynx, malposition and ineffective ventilation.

They found that insertion was more successful in the first attempt using guided technique, but success rates were similar after three attempts. The time taken for insertion was similar in the first attempt for three

techniques, but shorter for guided technique after three attempts. Hence they concluded that guided technique of Proseal laryngeal mask airway is more successful than introducer tool and digital techniques in patients with simulated difficult laryngoscopy using a rigid neck collar.

9] Taneja. S, Agarwalt. M, Dali.J.S, Agrawal.G et al[39] in 2009 compared the ease of Proseal laryngeal mask airway insertion and its fibreoptic view after placement using gum elastic bougie guided technique with conventional techniques. 96 patients belonging to ASA-PS 1&2 of 18-60yrs of age posted for elective surgeries were randomly selected and Proseal laryngeal mask airway was inserted using digital, introducer tool and gum elastic bougie guided techniques. Correct placement of Proseal laryngeal mask airway was assessed by clinical tests and fibreoptic visualization. Ease of insertion was assessed by number of attempts to successful insertion, effective airway time and number of patients requiring lateral approach for insertion. First attempt success rate was more for gum elastic bougie guided technique. Success rate after two attempts was also higher for bougie guided group. Time taken for successful placement was significantly shorter for gum elastic bougie guided technique. Fibreoptic view was significantly better for bougie guided group. Hence they concluded that gum elastic bougie guided technique of Proseal laryngeal mask airway has higher success rate and better fibreoptic view compared to other techniques.

10] Anand Kuppusamy, Naheed Azhar et al[2] in 2010 compared gum elastic bougie guided insertion of Proseal laryngeal mask airway with digital technique in sixty adult patients belonging to ASA-PS 1&2 of 18-80 years of

age with respect to number of attempts to successful placement, effective airway time, airway trauma during insertion, post-operative airway morbidity and hemodynamic response to insertion. Digital technique was performed according to the manufacturer's instructions. Gum elastic bougie guided technique involved priming the drain tube of Proseal laryngeal mask airway with gum elastic bougie and inserting the bougie into the esophagus with the help of a laryngoscope followed by railroading the Proseal laryngeal mask airway over the bougie. Then the bougie was removed. Number of attempts to successful insertion, airway trauma during insertion and hemodynamic response to insertion were comparable among the two study groups. Effective airway time and oropharyngeal leak pressures were more for bougie guided insertion and the results were statistically significant. Post-operative sore throat was more with digital insertion and dysphagia was more with bougie guided technique. Hence they concluded that gum elastic bougie guided technique is a very good alternative to digital technique of Proseal laryngeal mask airway insertion.

11] Chen.H.S, Yang.H.C, Chien.C.F, Spielberger.J, Hung.K.C, Chung.K.C et al[9] in 2011 compared the success rate of Proseal laryngeal mask airway insertion using Flexi-Slip Stylet with introducer tool technique. One hundred and sixty adult patients were randomly allocated into either introducer tool or Flexi-Slip Stylet group. Introducer tool technique was performed according to manufacturer's instructions. In Flexi-Slip Stylet guided method, the Flexi-Slip Stylet was introduced into the drain tube of Proseal laryngeal mask airway and it was bent until an angle of 90^0 was formed at the junction of airway tube and cuff of Proseal laryngeal mask

airway. Success rate at first attempt was the primary outcome measured. Times taken for successful insertion, visible blood staining and post-operative airway complications were also compared. First attempt success rate was more with Flexi-Slip Stylet guided technique [100%] when compared with introducer tool technique [86%]. The overall time taken for successful insertion was shorter for Flexi-Slip Stylet guided technique. Incidence of visible blood staining and post-operative complications were less in Flexi-Slip Stylet group. Hence they concluded that Flexi-Slip Stylet guided insertion of Proseal laryngeal mask airway has higher first attempt success rate, required lesser time for insertion and results in lesser post-operative complications than introducer tool technique.

12] Aaron. M. Joffe, Kristopher.M.Schroeder, John.A.Shelper, Richard Galgon et al[1] in 2012 reviewed the results of a randomized controlled trial comparing the air-Q intubating laryngeal mask airway and Proseal laryngeal mask airway. In the study, all Proseal laryngeal mask airway insertions were done by unassisted bougie guided technique. 48 patients of more than 18 yrs of age without any documented difficult airway were randomly selected and anaesthetized without using neuromuscular blocking agents. Drain tube of Proseal laryngeal mask airway was primed with well lubricated 15 Fr bougie. Proseal laryngeal mask airway and bougie were held as a unit and the straight end of the bougie was inserted into the esophagus with the help of a laryngoscope. Proseal laryngeal mask airway is then railroaded over it. Numbers of attempts to successful insertion, effective airway time and airway trauma during insertion were noted down. First attempt was successful in 47 patients and only one patient required three attempts for successful insertion.

Mean effective airway time was 28 seconds. Mean oropharyngeal leak pressure was 30 cm of H_20. Visible blood staining was found on four devices upon removal but there was no oropharyngeal injury. Most common post-operative complaints were sore throat and dysphagia. Hence they concluded that unassisted gum elastic bougie guided insertion of Proseal laryngeal mask airway can be accomplished quickly and safely without affecting the expected clinical performance of the device.

13] N.Jagannathan, L.E.Sohn, A.Sawardekar, J.Gordon, K.E.Langen and K.Anderson et al[20] in 2012 in a randomized trial compared Proseal laryngeal mask airway and laryngeal mask airway supreme in children.60 children of 6months-6yrs of age belonging to ASA-PS 1&2 weighing 10-20kg who were posted for elective outpatient surgeries were randomly divided into two groups and laryngeal mask airway supreme and Proseal laryngeal mask airway were inserted by standard insertion techniques. Airway leak pressure, ease and time of insertion, fibreoptic view, incidence of gastric insufflation, ease of gastric tube placement, quality of airway during maintenance of anaesthesia and post-operative complications were compared. They found that there were no statistically significant differences between laryngeal mask airway supreme and Proseal laryngeal mask airway with regard to time of insertion, airway leak pressure, fibreoptic view, ease of gastric access and complications. Hence they concluded that both the devices can be used as alternatives.

14] Maclean.J, Tripathy.D.K, Parthasarathy.S, Ravishankar.M et al[22] in 2013 conducted a study in patients with simulated restricted neck mobility in order to compare the ease of insertion and positioning of Proseal laryngeal mask airway using gum elastic bougie guided and introducer tool techniques. Sixty patients undergoing minor head and neck surgeries in supine position belonging to ASA-PS 1& 2 of 18-60 years of age were randomly divided into two groups. Patients were given anaesthesia using standard protocol. Proseal laryngeal mask airway insertion was done using either gum elastic bougie guided technique or introducer tool technique after opening the mouth using tongue depressor. Data was collected regarding ease of insertion, positioning, hemodynamic response to insertion and complications related to insertion. Gum elastic bougie guided technique took longer time for insertion. But it provided better positioning with lower $ETCO_2$ values when compared to introducer tool technique. Hemodynamic response was similar in both groups. The incidence of post-operative airway complications were more for introducer tool technique after 12hrs, but similar after 24hrs. Hence they concluded that even though time taken for insertion is longer for gum elastic bougie guided technique, it provides better positioning and lower $ETCO_2$ values when compared to introducer tool technique.

MATERIALS AND METHODS

STUDY DESIGN

This study is a prospective randomized comparative study

STUDY SETTING AND POPULATION

After obtaining written informed consent from the patients and clearance from the Institutional Ethics Committee, the study was conducted in minor gynaecological operation theatre, Institute of Obstetrics and Gynaecology, Egmore for a period of three months.

The study was carried out in 60 adult female patients in the age group of 21-60 years belonging to American Society of Anaesthesiologists Physical Status 1&2 posted for elective minor gynaecological surgeries at Institute of Obstetrics and Gynaecology, Egmore.

SAMPLE SIZE CALCULATION

Sample size was determined based on the study "Comparison of bougie-guided insertion of Proseal laryngeal mask airway with digital technique in adults" authored by Anand Kuppusamy and Naheed Azhar et al published in Indian Journal of Anaesthesia 2010; 54(1):35-39.

In this study, the success of gum elastic bougie guided insertion of Proseal laryngeal mask airway in the first attempt was higher (96.7%) when compared to the digital technique of Proseal laryngeal mask airway insertion (86.7%) with a difference of 10%.

DESCRIPTION:

- The confidence level is estimated at 95% with a z-value of 1.96.
- The confidence interval or margin of error is estimated at +/- 5.
- Assuming that 24 percent of the sample will have the specified attribute p% =96.7 and q%=3.3

  $n = p\% \times q\% \times [z/e\%]^2$

  $n = 96.7 \times 3.3 \times [1.96/5]^2$

  $n = 49.3$

Therefore 50 is the minimum sample size required for the study (n=25 in intervention arm and n=25 in control arm)

INCLUSION CRITERIA

1) Female patients belonging to 21 to 60 years
2) American Society of Anaesthesiologists Physical Status 1& 2
3) Body Mass Index between 20-25 kg/m^2
4) Modified Mallampati Score 1&2
5) Posted for elective minor gynaecological surgery
6) Given valid informed consent

EXCLUSION CRITERIA

1) Patients with difficult airway, Modified Mallampati Score 3&4

2) Patients with risk of aspiration

3) Patients with pre-existing lung disease

4) American Society of Anaesthesiologists Physical Status 3&4

5) Obesity

6) Pregnancy

7) All emergency surgeries

8) Patients with history of allergic reactions to the drugs used in the study

MATERIALS:

Monitors: ECG, NIBP, SpO_2, $ETCO_2$, Portex cuff pressure monitor

Airway devices: Gum elastic bougie, Proseal laryngeal mask airway, Laryngoscope

Drugs: Emergency drugs, Inj. Fentanyl, Inj. Propofol, Inj. Glycopyrolate, Sevoflurane, Inj. Ranitidine, Inj. Metoclopramide

Drager Fabius Anaesthesia machine

OUTCOMES MEASURED:

1) Number of attempts to successful placement

2) Effective airway time

3) Hemodynamic response to insertion

4) Airway trauma during insertion

5) Presence of visible blood staining

6) Post-operative airway morbidity

STUDY METHOD

Using closed envelope method, the patients were randomized into two groups

1) Group D: Digital technique for Proseal laryngeal mask airway insertion

2) Group B:Gum elastic bougie guided technique for Proseal laryngeal mask airway insertion

All the patients were fasted overnight. They were given anti-aspiration prophylaxis with Inj. Ranitidine 50mg IV and Inj. Metoclopramide 10mg IV 30 minutes prior to surgery. Patients were given premedication with Inj. Glycopyrrolate 0.2mg IV 30 minutes before surgery. Monitors [ECG, NIBP, SpO_2 and $ETCO_2$] were connected and baseline hemodynamic parameters were measured. The patients were preoxygenated with 100% oxygen for three minutes and then induced with Inj. Fentanyl 2microgram/kg IV and

Inj.Propofol 3mg/kg IV. Proseal laryngeal mask airway was inserted using digital/gum elastic bougie guided technique according to the study group.

GROUP D: DIGITAL TECHNIQUE

- Proseal laryngeal mask airway was selected according to the body weight of the patient
- The device is held in hand like a pen with the index finger kept in the introducer strap.
- The tip of the cuff is pressed against the hard palate and flattened against it.
- The device is introduced along the curvature of the hard palate by retaining the index finger in the introducer strap.
- The device is introduced further by flexion of wrist and extension of index finger until a definite resistance is felt.
- Before taking the index finger out of the mouth, device is pushed down by the non-dominant hand which prevents the laryngeal mask airway from getting dislodged and pulled out. It also helps to insert the device further inwards if it is not inserted fully using index finger.
- The Proseal laryngeal mask airway is then inflated and fixed

GROUP B: GUM ELASTIC BOUGIE GUIDED TECHNIQUE

- Well lubricated 16Fr gum elastic bougie was inserted into the drain tube of the Proseal laryngeal mask airway with its straight end protruding 30 cm from the distal end of the drain tube leaving sufficient length of bougie at the proximal end of the drain tube to get a grip of it.

- By doing gentle laryngoscopy, 5-10 cm of the straight end of the bougie was inserted into the esophagus.

- Laryngoscope was removed and the device was railroaded along the bougie using digital technique. Proximal end of the bougie was stabilized by an assistant.

- The bougie was removed after holding the device with the non-dominant hand.

- The Proseal laryngeal mask airway is then inflated and fixed.

- Proseal laryngeal mask airway was inserted by keeping the patient's head in sniffing position with cuff fully deflated and using midline approach. Insertion was considered as failure after three unsuccessful attempts

CRITERIA FOR FAILED INSERTION

1) Failed passage into pharynx

2) Malposition

   a. Air leak- Oropharynx [listening over mouth]

      -Gastric [auscultation over epigastrium]

      -Drain tube [placing lubricant over proximal drain tube]

   b. Negative suprasternal notch tap test

3) Ineffective ventilation

   a. Tidal volume<8ml/kg

   b. $ETCO_2$>45mm Hg

The time interval between picking up the laryngoscope or Proseal laryngeal mask airway and successful placement was recorded. After successful insertion, the cuff was inflated to a pressure of 60cm H_2O using cuff pressure monitor. After securing the Proseal laryngeal mask airway, presence of air leak over the mouth, stomach and drain tube was checked. Oropharyngeal leak pressure was measured in the integrated airway monitor in Drager Fabius anaesthesia machine by gradually increasing the tidal volume till air leak was heard over the mouth. Suprasternal notch tap test was performed by placing a membrane of soap solution over the proximal tip of the drain tube and observing for pulsations of membrane on tapping the suprasternal notch. Hemodynamic parameters [pulse rate, systolic blood

pressure, diastolic blood pressure, mean arterial pressure] were recorded before insertion and 1, 3, 5 and 10 minutes after insertion. Oxygen [1 liter], Nitrous oxide [2 liters] and sevoflurane 2% were used for maintenance of anaesthesia.

CUFF PRESSURE MONITOR

Peak inspiratory pressure was limited to 30cm H_20. Minimum tidal volume of 8ml/kg and $ETCO_2$<45mm Hg were maintained. During the procedure, occurrence of hypoxia [SpO_2<90%] or any other adverse events were noted. In case of failed insertion of Proseal laryngeal mask airway, surgery was allowed to continue after intubating the patient with endotracheal tube.

Proseal laryngeal mask airway was removed at the end of the procedure after adequately meeting the recovery criteria. Proseal laryngeal mask airway, bougie and laryngoscope were examined for presence of visible blood staining. Any evidence of trauma to the mouth, tongue and lips were noted down.

After 24 hours post-operatively, patients were enquired about the occurrence of

1) Sore throat [constant pain in the throat]

2) Dysphonia [difficulty in talking]

3) Dysphagia [difficulty in swallowing]

OBSERVATION AND RESULTS

This prospective randomized comparative study compared gum elastic bougie guided laryngoscope aided insertion of Proseal laryngeal mask airway with classical digital technique in sixty anaesthetized spontaneously breathing female patients undergoing elective minor gynaecological surgeries.

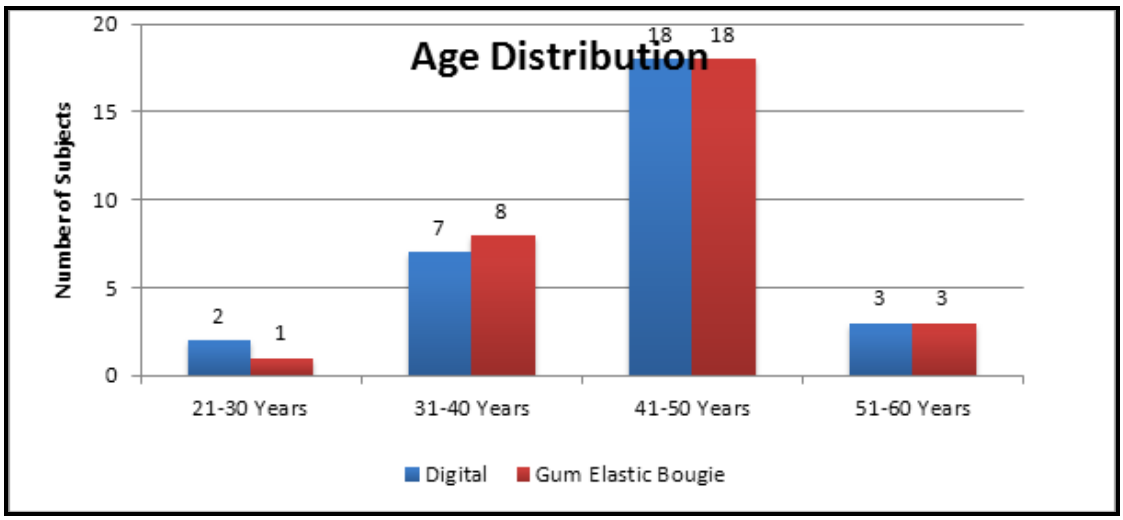
Descriptive statistics was done for all data and suitable statistical tests of comparison were done. Continuous variables were analyzed with the unpaired t test and categorical variables were analyzed with the Chi-Square Test and Fisher's Exact Test. Statistical significance was taken as $P < 0.05$. The data was analyzed using EpiInfo software (7.1.0.6 version; Center for disease control, USA) and Microsoft Excel 2010.

All data obtained were collected and compiled. The summary of results is described below.

Groups	Intervention Used	Procedure
Digital(D)	Digital technique	Proseal laryngeal mask airway insertion in anaesthetized spontaneously breathing patients undergoing elective minor gynecological surgeries
Gum Elastic Bougie(B)	Gum Elastic Bougie guided technique	

AGE

The study was conducted in female patients belonging to 21-60 years of age.

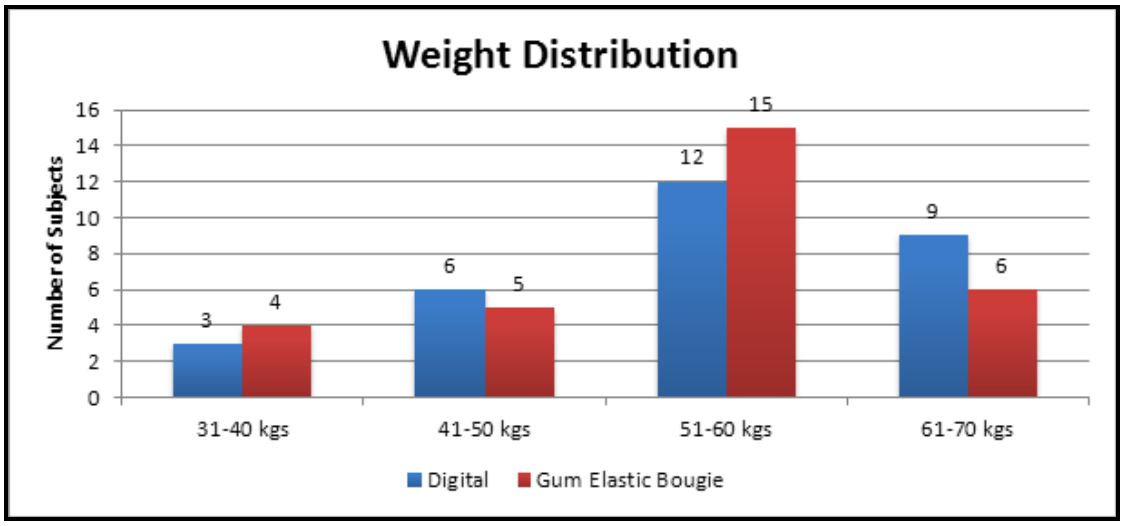


Age Distribution	Digital	%	Gum Elastic Bougie	%
21-30 years	2	6.67	1	3.33
31-40 years	7	23.33	8	26.67
41-50 years	18	60.00	18	60.00
51-60 years	3	10.00	3	10.00
Total	30	100	30	100

Age Distribution	Digital	Gum Elastic Bougie
N	30	30
Mean	42.77	43.20
SD	6.92	6.88
P value Unpaired t-test	0.8086	

Most of the patients in digital technique group were clustered in 41-50 years age group (n=18, 60%) with a mean age of 42.77 years. In the gum elastic bougie group of patients, the clustering was in the same age group as digital group (n=18, 60%) with a mean age of 43.20 years. By conventional criteria the association between the intervention groups and age distribution is considered to be not statistically significant since $p > 0.05$ as per unpaired t-test.

WEIGHT



Weight Distribution	Digital	%	Gum Elastic Bougie	%
31-40 kg	3	10.00	4	13.33
41-50 kg	6	20.00	5	16.67
51-60 kg	12	40.00	15	50.00
61-70 kg	9	30.00	6	20.00
Total	30	100	30	100

Weight Distribution	Digital	Gum Elastic Bougie
N	30	30
Mean	53.73	52.43
SD	5.11	4.87
P value Unpaired t-test	1.0087	

Most of the patients in digital technique group were clustered in the 51-60 kg class interval (n=12, 40%) with a mean weight of 53.73 kg. In the gum elastic bougie group of patients, the clustering was in the same class interval (n=15, 50%) as digital group with a mean weight of 52.43 kg. By conventional criteria the association between the intervention groups and weight is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.

Hence both the study groups are statistically comparable with respect to the demographic variables like age and weight.

NUMBER OF ATTEMPTS TO SUCCESSFUL PLACEMENT

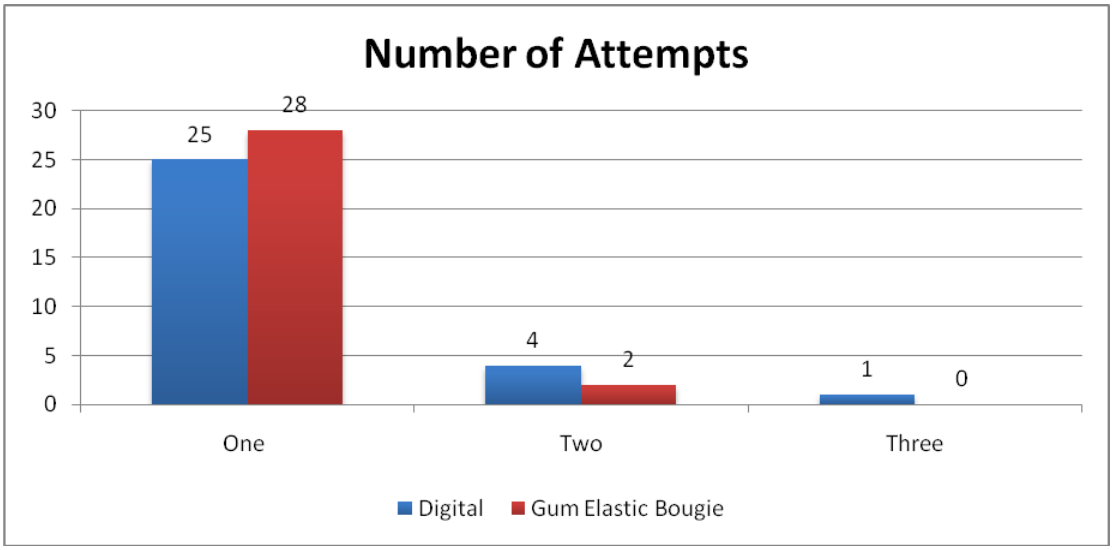
Successful placement of Proseal laryngeal mask airway is defined by

1) Square wave pattern of capnography

2) Absence of air leak over mouth, stomach and drain tube

3) Positive suprasternal notch tap test

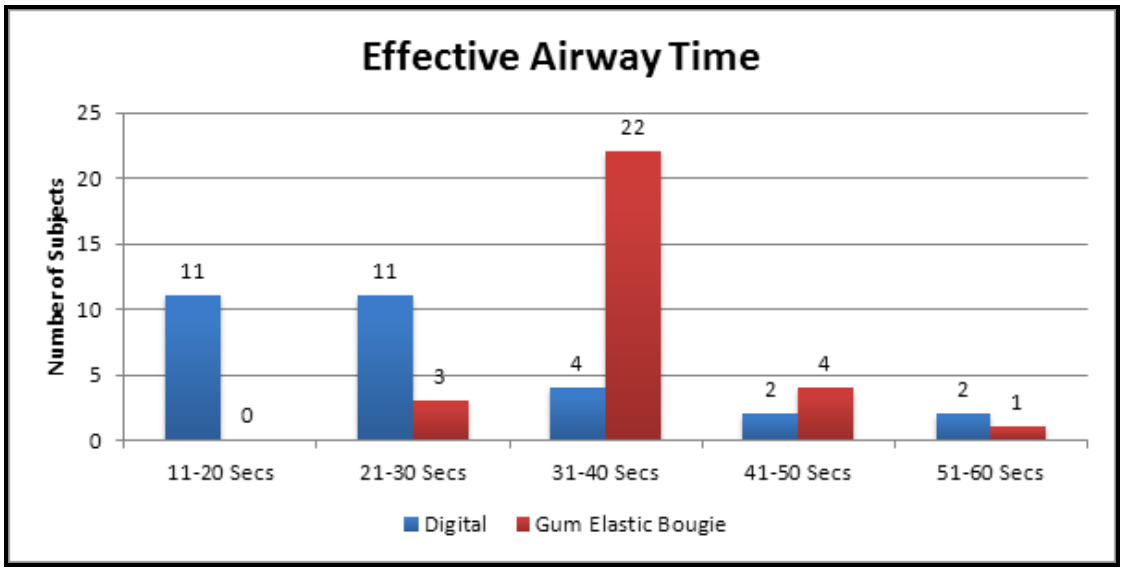
4) Effective ventilation [tidal volume> 8ml/kg, $ETCO_2$< 45 mm Hg]



Number of Attempts	Digital	%	Gum Elastic Bougie	%	P value Fisher's Exact Test
One	25	83.33	28	93.33	0.5223
Two	4	13.33	2	6.67	> 0.9999
Three	1	3.33	0	0.00	> 0.9999
Total	30	100	30	100	

Gum elastic bougie guided insertion of Proseal laryngeal mask airway was successful in 28/30 (93.33%) patients in first attempt while only two patients (6.67%) required second attempt. But digital technique of Proseal laryngeal mask airway insertion was successful only in 25/30(83.33%) patients in the first attempt and four patients (13.33%) required second attempt and one patient (3.33%) required third attempt. By conventional criteria the association between the intervention groups and number of attempts is considered to be not statistically significant since $p > 0.05$ as per Fisher's exact test.

EFFECTIVE AIRWAY TIME



Effective Airway Time	Digital	%	Gum Elastic Bougie	%
11-20 seconds	11	36.67	0	0.00
21-30 seconds	11	36.67	3	10.00
31-40 seconds	4	13.33	22	73.33
41-50 seconds	2	6.67	4	13.33
51-60 seconds	2	6.67	1	3.33
Total	30	100	30	100

Effective Airway Time	Digital	Gum Elastic Bougie
N	30	30
Mean	25.47	36.17
SD	11.85	6.60
P value : Unpaired t-test	0.0001	

By conventional criteria the association between the intervention groups and effective airway time is considered to be statistically significant since $p < 0.05$ as per unpaired t-test. This indicates that there is a true difference among intervention groups and the difference is significant.

In simple terms, most of the digital group patients were clustered in the 11-20 seconds (n=11, 36.67%) and 21-30 seconds class interval (n=11, 36.67%) with a mean effective airway time of 25.47 seconds. Similarly in the gum elastic bougie group majority of the patients were clustered in the 31-40 seconds class interval (n=22, 73.33%) with a mean effective airway time of 36.17 seconds with a p-value of 0.0001. The mean effective airway time was meaningfully less in digital intervention group compared to gum elastic bougie intervention group by a mean time of 10.70 seconds. This significant difference of 30% reduction in mean effective airway time among patients

belonging to digital intervention group compared to gum elastic bougie intervention group is true and has not occurred by chance. In this study we can safely conclude that gum elastic bougie guided technique for Proseal laryngeal mask airway insertion results in significantly longer effective airway time compared to digital technique when used in anaesthetized spontaneously breathing patients undergoing elective minor gynaecological surgeries.

FAILED INSERTION

CRITERIA FOR FAILED INSERTION:

1) Failed passage into pharynx

2) Malposition

a) Air leak- Oropharynx [listening over mouth]

- Gastric [auscultation over epigastrium]

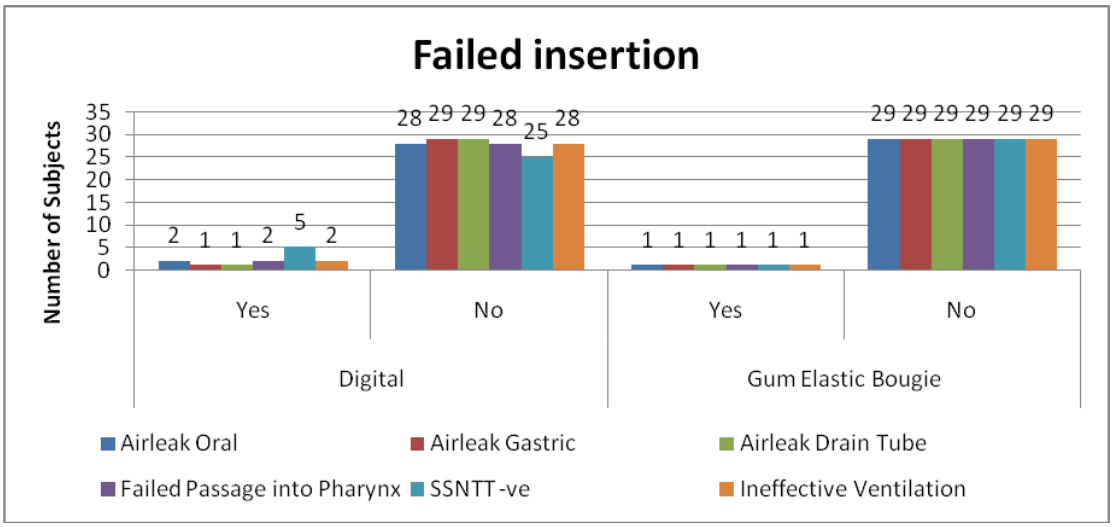
- Drain tube [placing lubricant over proximal drain tube]

b) Negative suprasternal notch tap test

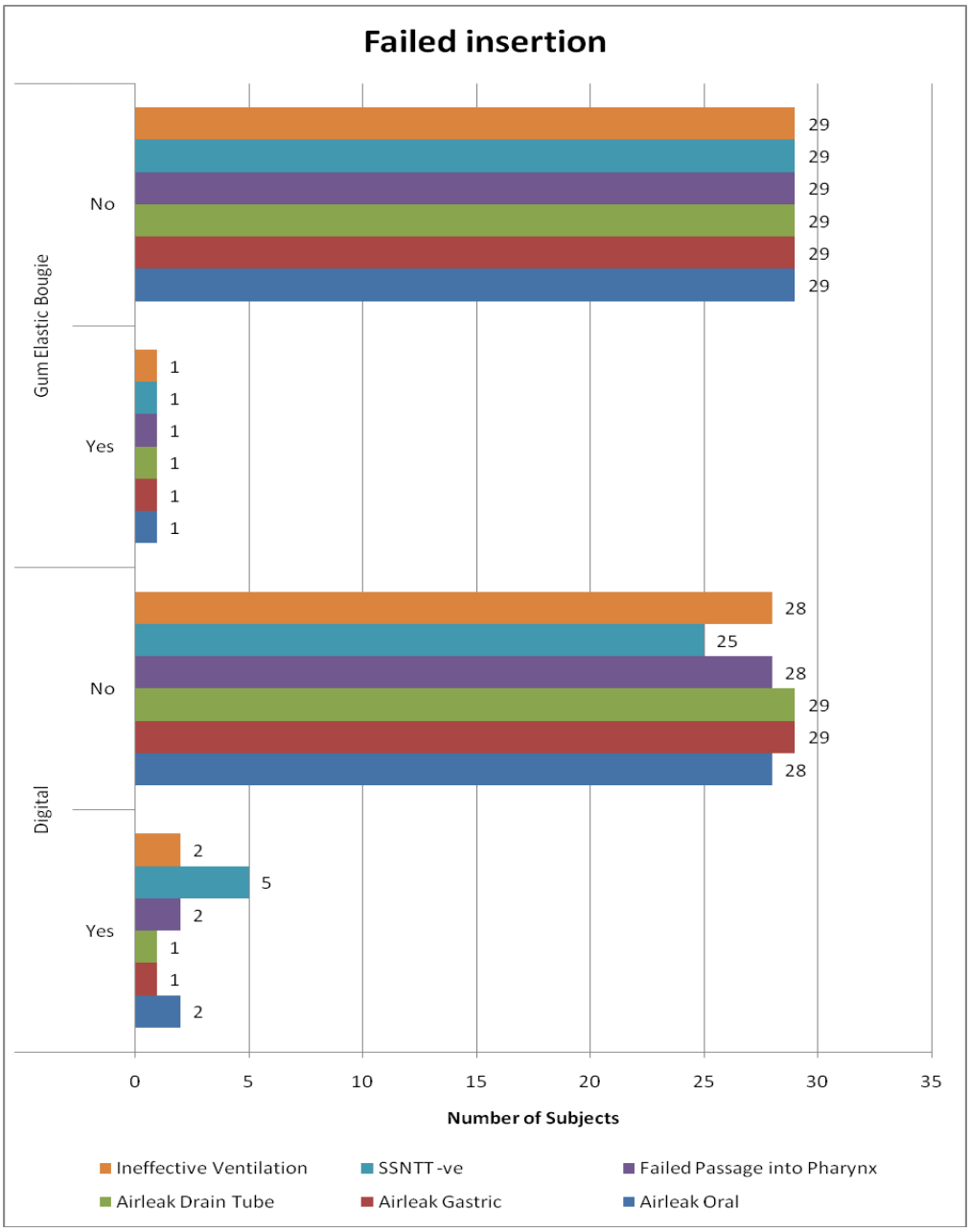
3) Ineffective ventilation

a) Tidal volume <8ml/kg

b) $ETCO_2$ >45mm Hg



Failed insertion	Digital		Gum Elastic Bougie		P value: Fisher's Exact Test
	Yes	No	Yes	No	
Air leak Oral	2	28	1	29	> 0.9999
Air leak Gastric	1	29	1	29	> 0.9999
Air leak Drain Tube	1	29	1	29	> 0.9999
Failed Passage into Pharynx	2	28	1	29	> 0.9999
SSNTT -ve	5	25	1	29	0.4367
Ineffective Ventilation	2	28	1	29	>0.9999



Most common cause of failed insertion of Proseal laryngeal mask airway in digital group was negative suprasternal notch tap test (5/30). In gum elastic bougie guided group, negative suprasternal notch tap test contributed to failed insertion in only one patient (1/30). By conventional criteria, failed insertion of Proseal laryngeal mask airway due to negative suprasternal notch

tap test is considered to be not statistically significant since p>o.o5 as per Fisher's exact test.

Failed passage into pharynx contributed to failed insertion in two patients (2/30) in digital group and only one patient (1/30) in gum elastic bougie guided group. Hence, by conventional criteria association between the intervention group and failed passage into pharynx is considered to be not statistically significant as p value >0.05 as per Fisher's exact test

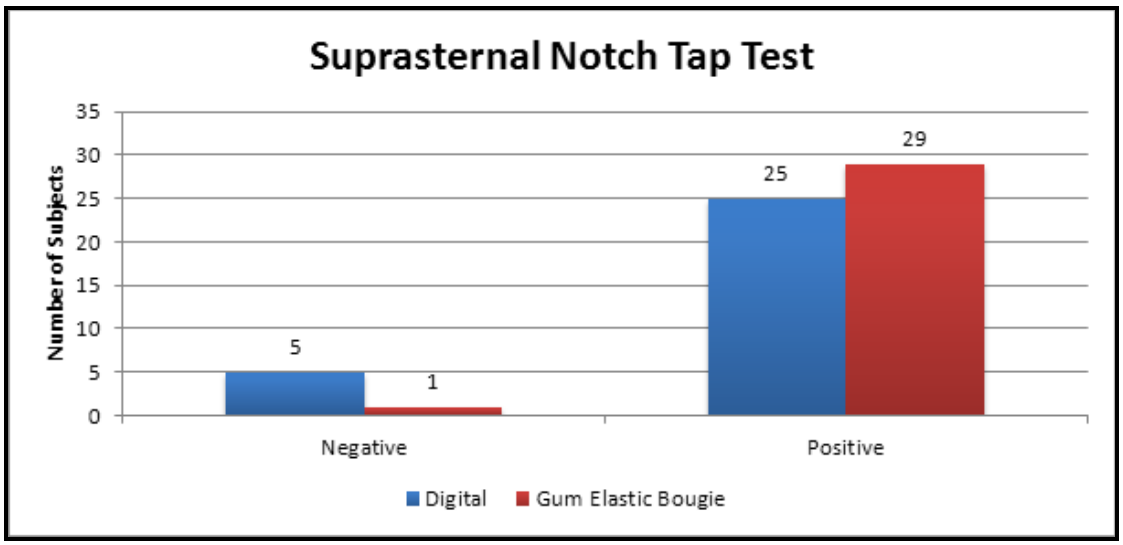
Oral air leak caused failed insertion in two patients (2/30) in digital group and one patient (1/30) in gum elastic bougie guided group. By conventional criteria, failed insertion due to oral air leak is not statistically significant as p value >0.05

Gastric air leak contributed to failed insertion in one patient in both groups. By conventional criteria association between gastric air leak is statistically not significant as p>0.05

Drain tube air leak contributed to failed insertion in one patient in both groups. Hence by conventional criteria association between drain tube air leak is statistically not significant as p>0.05

Ineffective ventilation contributed to failed insertion in two patients (2/30) in digital group and one patient (1/30) in gum elastic bougie guided group. By conventional criteria, ineffective ventilation is not statistically significant as p value >0.05

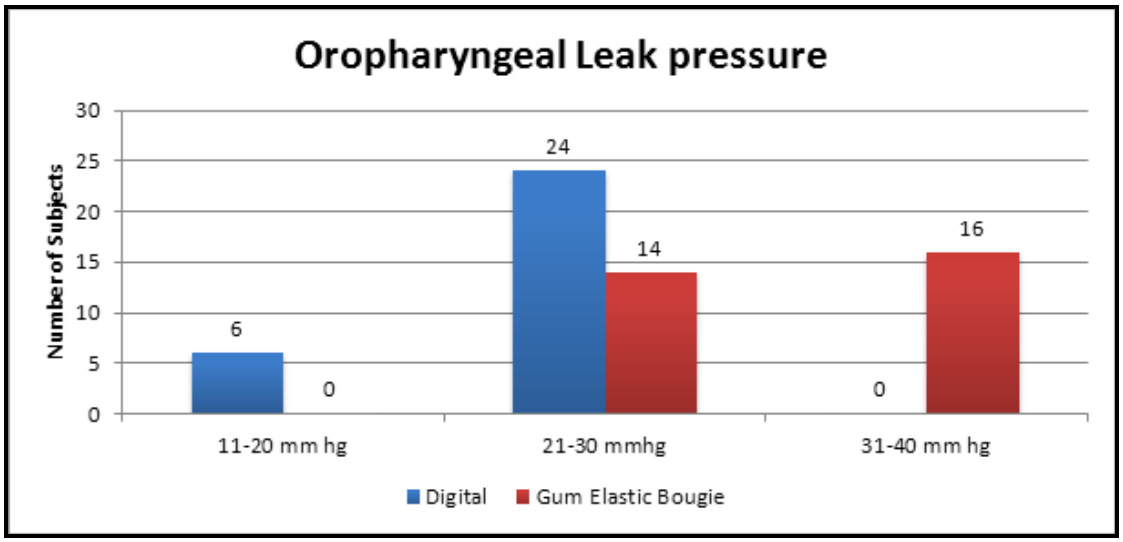
SUPRASTERNAL NOTCH TAP TEST



Suprasternal Notch Tap Test	Digital	%	Gum Elastic Bougie	%	P value Fisher's Exact Test
Negative	5	16.67	1	3.33	0.1945
Positive	25	83.33	29	96.67	
Total	30	100	30	100	

Most of the digital group patients had positive suprasternal notch tap test (n=25, 83.33%). Similarly in the gum elastic bougie group, majority of the patients had positive suprasternal notch tap test (n=29, 96.67%). By conventional criteria the association between the intervention groups and suprasternal notch tap test is considered to be not statistically significant since $p > 0.05$ as per Fisher's exact test.

OROPHARYNGEAL LEAK PRESSURE

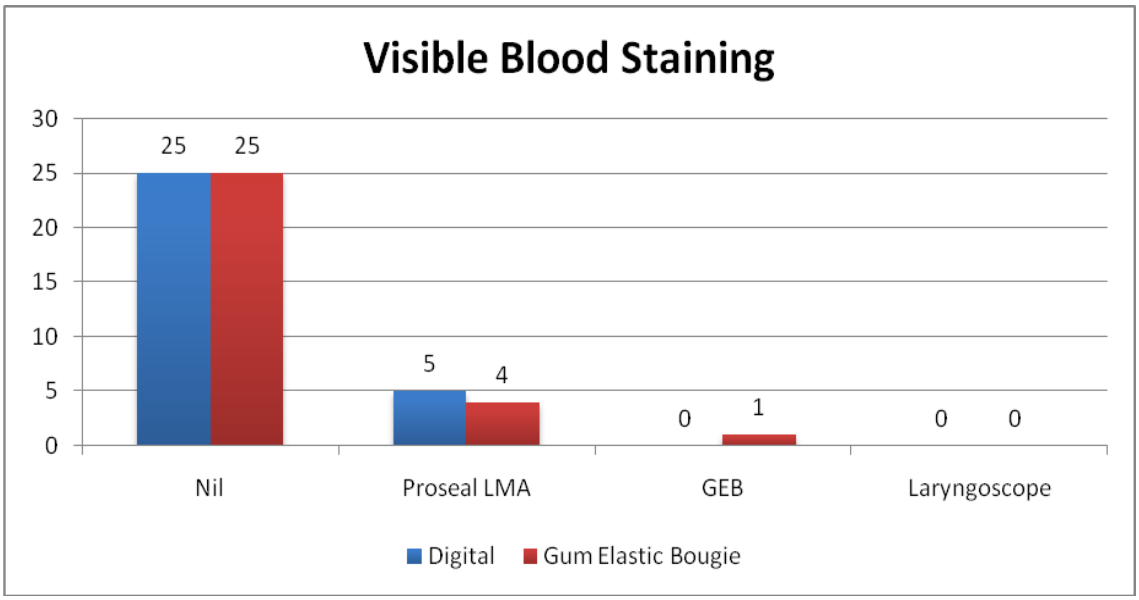


Oropharyngeal Leak pressure	Digital	%	Gum Elastic Bougie	%
11-20 mm Hg	6	20.00	0	0.00
21-30 mmHg	24	80.00	14	46.67
31-40 mm Hg	0	0.00	16	53.33
Total	30	100	30	100

Oropharyngeal Leak pressure	Digital	Gum Elastic Bougie
N	30	30
Mean	23.57	31.27
SD	2.84	4.27
P value Unpaired t-test	0.0000	

By conventional criteria the association between the intervention groups and oropharyngeal leak pressure is considered to be statistically significant since $p < 0.05$ as per unpaired t- test. This indicates that there is a true difference among intervention groups and the difference is significant. In simple terms, most of the digital group patients were clustered in the 21-30 mm Hg class interval (n=24, 80%) with a mean oropharyngeal leak pressure of 23.57 mm Hg. Similarly, in the gum elastic bougie group majority of the patients were clustered in the 31-40 mm Hg class interval (n=16, 53.33%) with a mean oropharyngeal leak pressure of 31.27 mm Hg with a p-value of 0.0000. The mean oropharyngeal leak pressure was meaningfully higher in gum elastic bougie intervention group compared to digital intervention group by a mean of 7.70 mm Hg. This significant difference of 25% increase in mean oropharyngeal leak pressure among patients belonging gum elastic bougie intervention group compared to digital intervention group is true and has not occurred by chance. In this study we can safely conclude that gum elastic bougie guided technique for Proseal laryngeal mask airway insertion results in significantly higher oropharyngeal leak pressure compared to digital technique when used in anaesthetized spontaneously breathing patients undergoing elective minor gynaecological surgeries.

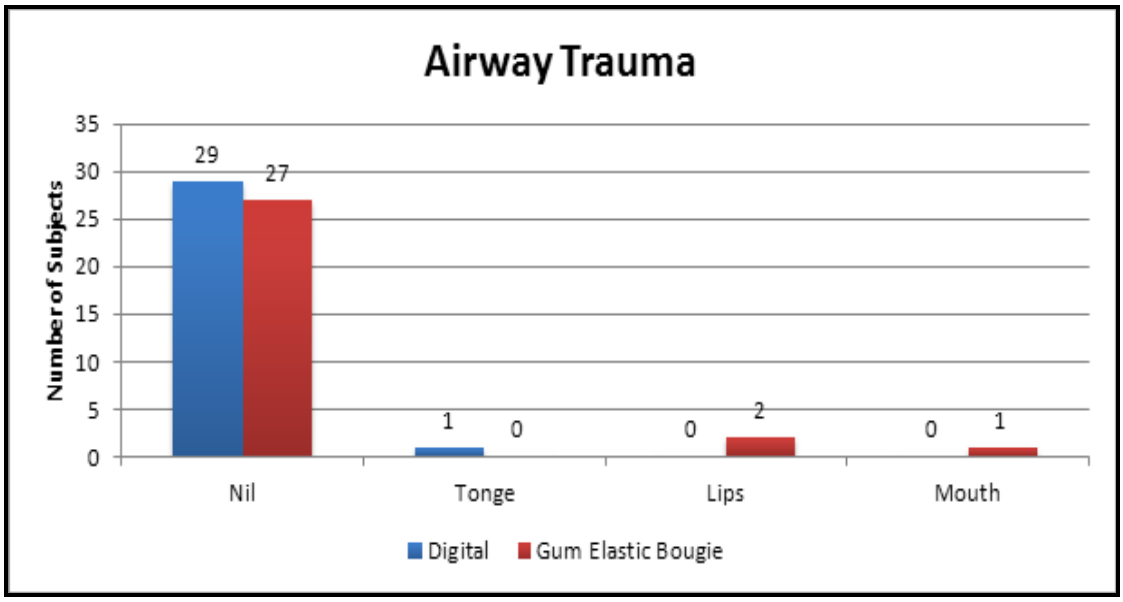
VISIBLE BLOOD STAINING



Visible Blood Staining	Digital	%	Gum Elastic Bougie	%	P value : Fisher's Exact Test
Nil	25	83.33	25	83.33	> 0.9999
Proseal LMA	5	16.67	4	13.33	> 0.9999
GEB	0	0.00	1	3.33	> 0.9999
Laryngoscope	0	0.00	0	0.00	1.0000
Total	30	100	30	100	

Most of the digital group patients had no visible blood staining (n=25, 83.33%). Similarly in the gum elastic bougie group majority of the patients had no visible blood staining (n=25, 83.33%).Visible blood staining over Proseal laryngeal mask airway was present in 4/30 patients (13.33%) in gum elastic bougie guided group and 5/30 patients (16.67%) in digital group. There was no visible blood staining of laryngoscope in both groups. Gum elastic bougie was blood stained in only one patient (3.33%) among bougie guided group. Hence, by conventional criteria the association between the intervention groups and visible blood staining is considered to be not statistically significant since $p > 0.05$ as per Fisher's exact test.

AIRWAY TRAUMA

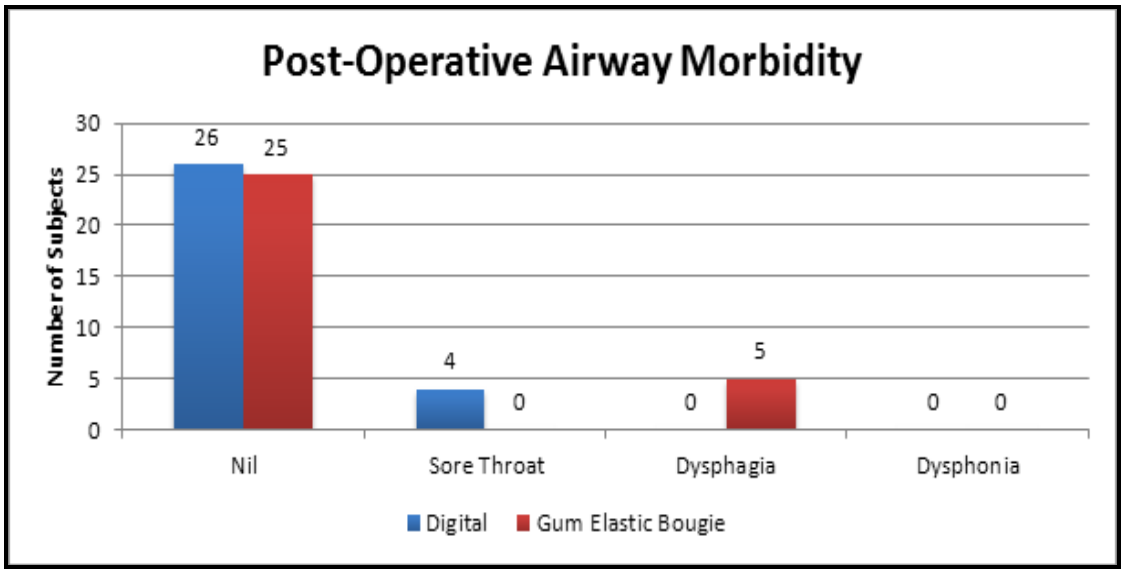


Airway Trauma	Digital	%	Gum Elastic Bougie	%	P value : Fisher's Exact Test
Nil	29	96.67	27	90.00	0.612
Tongue	1	3.33	0	0.00	> 0.9999
Lips	0	0.00	2	6.67	0.4915
Mouth	0	0.00	1	3.33	> 0.9999
Total	30	100	30	100	

Most of the digital group patients had no airway trauma (n=29, 96.67%). Similarly in the gum elastic bougie group majority of the patients belonged to no airway trauma group (n=27, 90%). The major airway trauma noticed in digital group patients was in tongue (n=1, 3.33%) and in gum elastic bougie group was in lips (n=2, 6.67%). By conventional criteria the association between the intervention groups and airway trauma is considered to be not statistically significant since $p > 0.05$ as per Fisher's exact test.

POST-OPERATIVE AIRWAY MORBIDITY

Post-operative sore throat, dysphagia and dysphonia were assessed 24hours post-operatively.



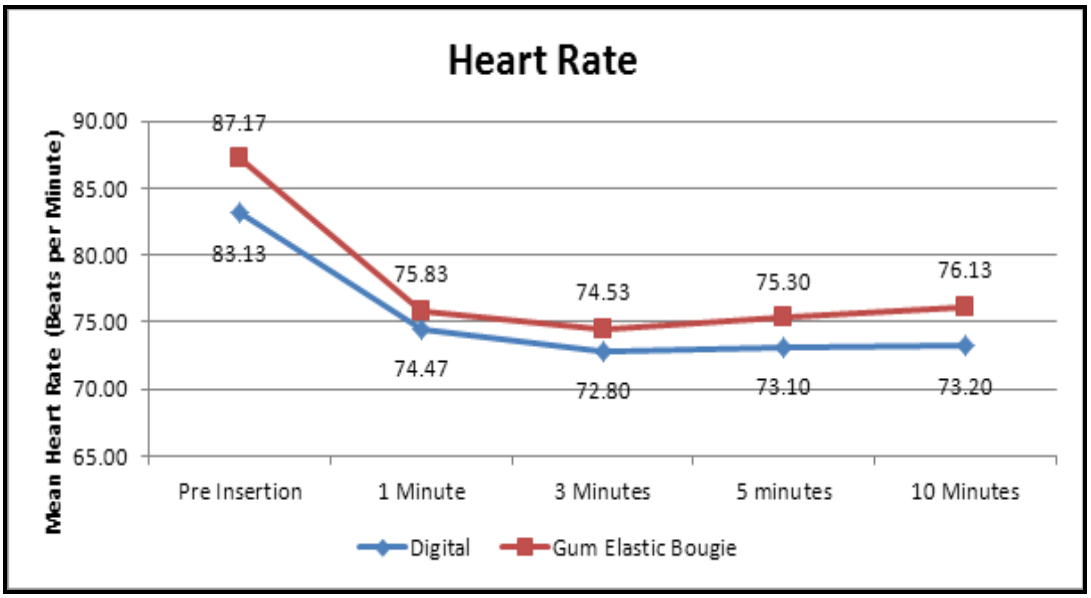
Post-Operative Airway Morbidity	Digital	%	Gum Elastic Bougie	%	P value Fishers Exact Test
Nil	26	86.67	25	83.33	> 0.9999
Sore Throat	4	13.33	0	0.00	0.1124
Dysphagia	0	0.00	5	16.67	0.0422
Dysphonia	0	0.00	0	0.00	1.0000
Total	30	100	30	100	

By conventional criteria the association between the intervention groups and dysphagia is considered to be statistically significant since $p < 0.05$ as per Fishers exact test. This indicates that there is a true difference among intervention groups with respect to dysphagia and the difference is significant. In simple terms, most of the digital group patients were clustered in the nil postoperative airway morbidity class interval (n=26, 86.67%). Similarly in the gum elastic bougie group majority of the patients were clustered in the nil postoperative airway morbidity class interval (n=25, 83.33%) with a p value of >0.9999. The major postoperative airway morbidity noticed in digital group patients is sore throat (n=4, 13.33%, p = 0.1124) and in gum elastic bougie group is dysphagia (n=5, 16.67%, p = 0.0422) . The incidence of dysphagia as postoperative airway morbidity is meaningfully less in digital intervention group compared to gum elastic bougie intervention group by 5 study subjects. This significant difference of 16.67% reduction in dysphagia among patients belonging to digital intervention group compared to gum elastic bougie intervention group is true and has not occurred by chance. In this study we can safely conclude that digital technique for Proseal laryngeal mask airway insertion results in significantly lowered incidence of dysphagia compared to gum elastic bougie guided technique when used in anaesthetized spontaneously breathing patients undergoing elective minor gynaecological surgeries

HEMODYNAMIC PARAMETERS

Heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure were measured before insertion and one minute, three minutes, five minutes and ten minutes after insertion of Proseal laryngeal mask airway.

HEART RATE

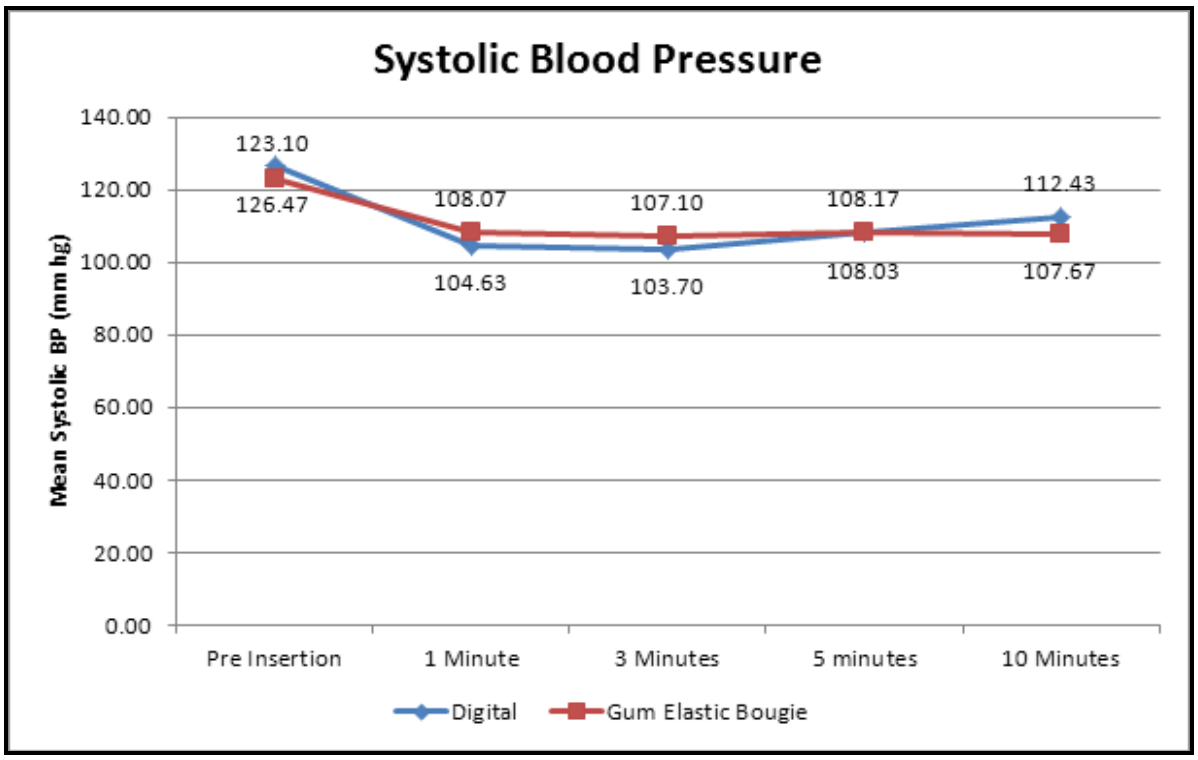


Association between intervention groups and heart rate is considered to be not statistically significant

Heart Rate	Pre Insertion		1 Minute		3 Minutes		5 minutes		10 Minutes	
	Digital	Gum Elastic Bougie	Digital	Gum Elastic Bougie	Digital	Gum Elastic Bougie	Digital	Gum Elastic Bougie	Digital	Gum Elastic Bougie
N	30	30	30	30	30	30	30	30	30	30
Mean	83.13	87.17	74.47	75.83	72.80	74.53	73.10	75.30	73.20	76.13
SD	12.37	11.97	9.79	9.83	8.54	9.12	9.16	8.11	8.51	8.26
P value Unpaired t-test	0.2046		0.5915		0.4504		0.3289		0.1806	

Most of the digital group patients had mean heart rates ranging from 83 beats/minute (83.13) to 73 beats/minute (73.20) between pre-insertion and 10 minutes intra-operatively. Similarly the gum elastic bougie group patients had mean heart rates ranging from 87 beats/minute (87.17) to 76 beats/minute (76.13) between pre-insertion and 10 minutes intra-operatively. By conventional criteria the association between the intervention groups and heart rate is considered to be not statistically significant since $p>0.05$ as per unpaired t- test.

SYSTOLIC BP

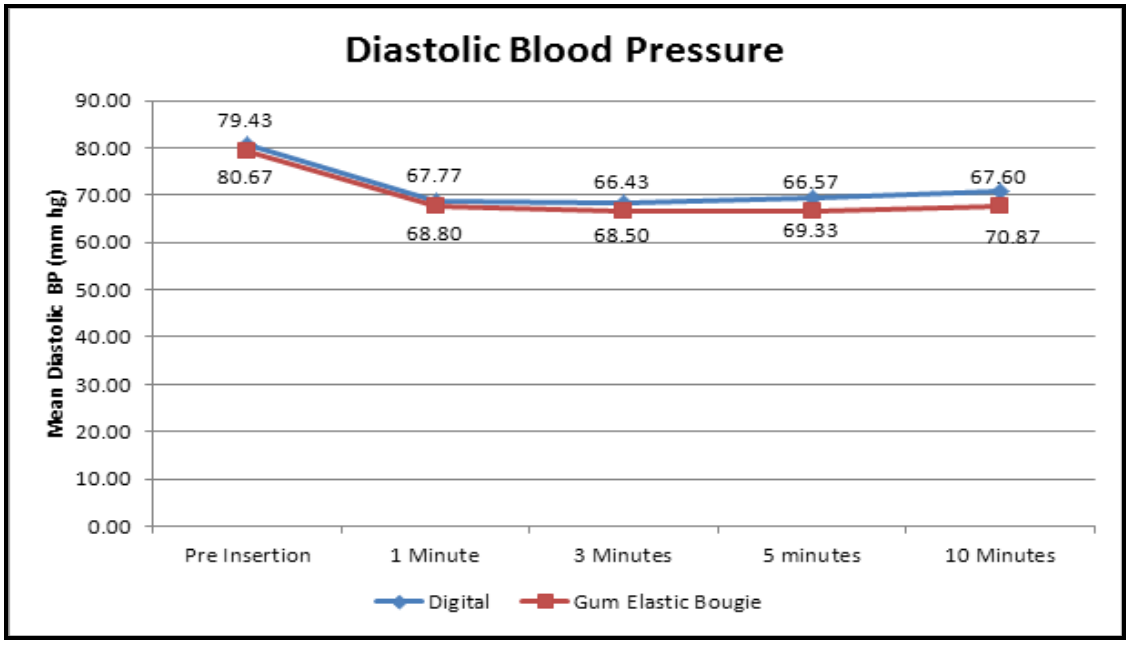


Association between intervention groups and systolic blood pressure is considered to be not statistically significant

Systolic Blood Pressure	Pre Insertion		1 Minute		3 Minutes		5 minutes		10 Minutes	
	Digital	Gum Elastic Bougie	Digital	Gum Elastic Bougie	Digital	Gum Elastic Bougie	Digital	Gum Elastic Bougie	Digital	Gum Elastic Bougie
N	30	30	30	30	30	30	30	30	30	30
Mean	126.47	123.10	104.63	108.07	103.70	107.10	108.03	108.17	112.43	107.67
SD	9.94	11.38	10.71	9.53	8.96	9.22	7.87	9.68	7.13	7.78
P value Unpaired t-test	0.2273		0.1948		0.1529		0.9535		0.1633	

Most of the digital group patients had mean systolic blood pressure ranging from 126.47 mm Hg to 112.43 mm Hg between pre-insertion and 10 minutes intraoperatively. Similarly the gum elastic bougie group patients had mean systolic blood pressure ranging from 123.10 mm Hg to 107.67 mm Hg between pre-insertion and 10 minutes intra-operatively. By conventional criteria the association between the intervention groups and systolic blood pressure is considered to be not statistically significant since $p > 0.05$ as per unpaired t- test.

DIASTOLIC BP

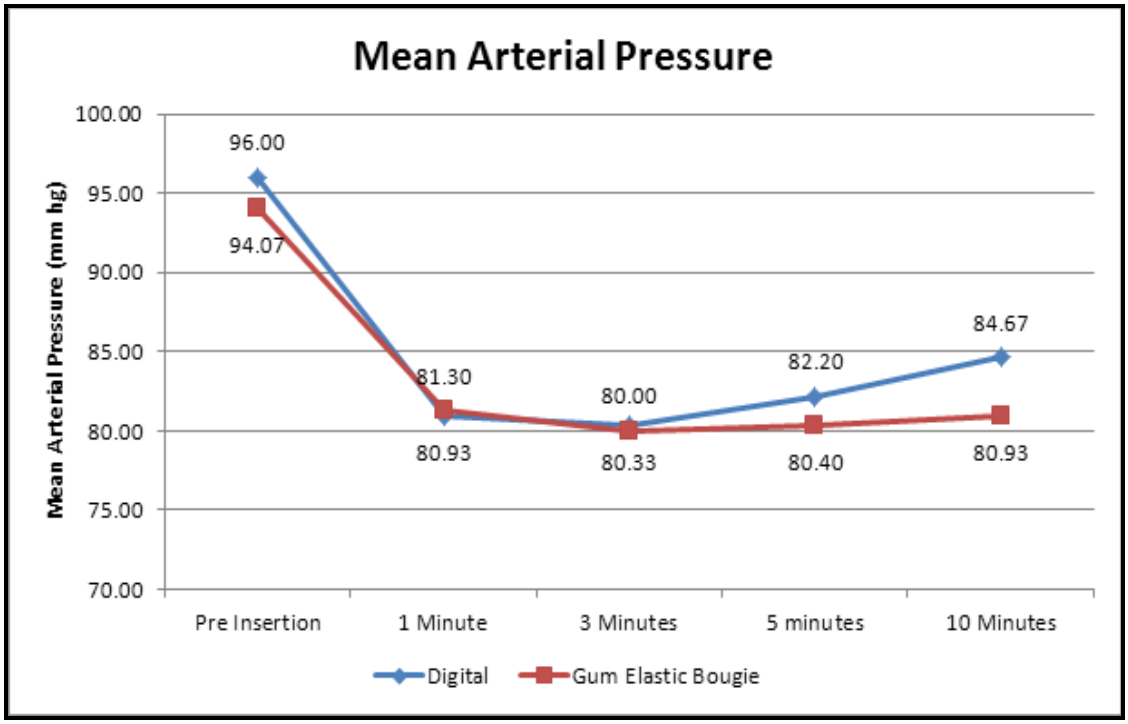


Association between intervention groups and diastolic blood pressure is considered to be not statistically significant

Diastolic Blood Pressure	Pre Insertion		1 Minute		3 Minutes		5 minutes		10 Minutes	
	Digital	Gum Elastic Bougie	Digital	Gum Elastic Bougie	Digital	Gum Elastic Bougie	Digital	Gum Elastic Bougie	Digital	Gum Elastic Bougie
N	30	30	30	30	30	30	30	30	30	30
Mean	80.67	79.43	68.80	67.77	68.50	66.43	69.33	66.57	70.87	67.60
SD	8.25	9.77	6.76	8.54	5.83	6.34	6.38	8.12	5.81	8.50
P value Unpaired t-test	0.5993		0.6055		0.1939		0.1481		0.0883	

Most of the digital group patients had mean diastolic blood pressure ranging from 80.67 mm Hg to 70.87 mm Hg between pre-insertion and 10 minutes intraoperatively. Similarly the gum elastic bougie group patients had mean diastolic blood pressure ranging from 79.43 mm Hg to 67.60 mm Hg between pre-insertion and 10 minutes intra-operatively. By conventional criteria the association between the intervention groups and diastolic blood pressure is considered to be not statistically significant since $p > 0.05$ as per unpaired t-test.

MEAN ARTERIAL PRESSURE



Association between intervention groups and mean arterial pressure is considered to be not statistically significant

Mean Arterial Pressure	Pre Insertion		1 Minute		3 Minutes		5 minutes		10 Minutes	
	Digital	Gum Elastic Bougie	Digital	Gum Elastic Bougie	Digital	Gum Elastic Bougie	Digital	Gum Elastic Bougie	Digital	Gum Elastic Bougie
N	30	30	30	30	30	30	30	30	30	30
Mean	96.00	94.07	80.93	81.30	80.33	80.00	82.20	80.40	84.67	80.93
SD	7.91	9.96	7.31	8.47	6.19	6.74	5.61	8.27	5.39	7.49
P value Unpaired t-test	0.4087		0.8581		0.8426		0.3283		0.3110	

Most of the digital group patients had mean value of mean arterial pressure ranging from 96.00 mm Hg to 84.67 mm Hg between pre-insertion and 10 minutes intra-operatively. Similarly the gum elastic bougie group patients had mean value of mean arterial pressure ranging from 94.07 mm Hg to 80.93 mm Hg between pre-insertion and 10 minutes intra-operatively. By conventional criteria the association between the intervention groups and mean arterial pressure is considered to be not statistically significant since $p > 0.05$ as per unpaired t- test.

DISCUSSION

Proseal laryngeal mask airway is an acceptable method to maintain a clear airway. Due to the presence of drain tube it reduces the risk of gastric insufflation. Due to the modified features of its cuff, it helps to provide positive pressure ventilation.

Different techniques have been developed for insertion of Proseal laryngeal mask airway to prevent its malposition leading to ineffective ventilation. Our study compared two among such techniques of Proseal laryngeal mask airway insertion namely classical digital technique and gum elastic bougie guided technique. The study was conducted in 60 adult female patients undergoing elective minor gynaecological surgeries under general anaesthesia with spontaneous ventilation.

The demographic variables (age, weight) were comparable. Hence, we proceeded with comparing the other study variables.

Number of attempts to successful placement: Our study revealed that success rate of insertion of Proseal laryngeal mask airway in the first attempt was higher for gum elastic bougie guided group when compared to digital insertion group. But number of attempts to successful placement is found to be not statistically significant between the two groups. Anand Kuppusamy, Naheed Azhar et al[2] in 2010 compared gum elastic bougie guided insertion of Proseal laryngeal mask airway with digital technique. In their study, first attempt success rate was higher for gum elastic bougie guided insertion. This is similar to the results obtained in our study. This also correlates with the results of M. Lopez Gil, J. Brimacombe and C. Keller et al[24] in2006.

Effective airway time: In our study, time taken to establish an effective airway was significantly more for gum elastic bougie guided technique (36.17 seconds) when compared to digital technique (25.47 seconds). Anand Kuppusamy and Naheed Azhar et al[2] in their study in 2010 compared gum elastic bougie guided insertion of Proseal laryngeal mask airway with digital technique. In their study, effective airway time was longer in gum elastic bougie guided technique when compared to digital technique. This result is similar to the result of our study. This result also correlates with the findings of M. Lopez Gil, J. Brimacombe and C. Keller et al[24] in 2006.

Failed insertion: In our study, most common cause of failed insertion was found to be negative suprasternal notch tap test. It contributed to failed insertion in 16.67% of cases in digital technique and 3.33% of cases in gum elastic bougie guided technique. Air leak (oral/ gastric/ drain tube), ineffective ventilation and failed passage into the pharynx were the other causes of failed insertion. Incidence of failed insertion was more with digital technique when compared to gum elastic bougie guided technique. Anand Kuppusamy and Naheed Azhar et al[2] in their study in 2010 also found that negative suprasternal notch tap test was the most common cause of failed insertion. In their study, incidence of failed insertion was more with digital technique. These results are similar to the results of our study.

Oropharyngeal leak pressure: In our study, oropharyngeal leak pressure was significantly higher in gum elastic bougie guided group (31.27mm Hg) when compared to digital group (23.57mm Hg). Anand Kuppusamy, Naheed Azhar et al[2] in their study in 2010 found that oropharyngeal leak pressure was 23.13 mm Hg in digital technique and 30.63 mm Hg in gum elastic bougie guided

technique. Thus, the findings of this study are similar to the results of our study.

Visible blood staining: In our study, there was no significant visible blood staining on Proseal laryngeal mask airway, gum elastic bougie and laryngoscope in digital and gum elastic bougie guided technique. This observation is similar to the studies of Brimacombe. J and Keller. C et al[3] in 2004, M. Lopez Gil and J. Brimacombe et al[24] in 2006 and Anand Kuppusamy and Naheed Azhar et al[2] in 2010.

Airway trauma during insertion: In our study, there was no significant trauma to lips, tongue and mouth in the two study groups. This result is similar to the studies of Howath. A and Brimacombe. J et al[19] in 2002, J. Brimacombe and C. Keller et al[3] in 2004 and Anand Kuppusamy and Naheed Azhar et al[2] in 2010.

Post-operative airway morbidity: The incidence of dysphagia was significantly more in gum elastic bougie guided group, but none of the patients had dysphonia or sore throat. Most common airway morbidity in patients of digital group was sore throat but none of the patients had dysphagia or dysphonia. These results are similar to the studies of Anand Kuppusamy and Naheed Azhar et al[2] in 2010.

Hemodynamic response to insertion: In our study, there was no significant hemodynamic response (alteration in heart rate, systolic, diastolic and mean arterial pressure) to Proseal laryngeal mask airway insertion using both techniques. This observation is similar to the studies of Howath. A, Brimacombe. J and Keller. C et al[19] in 2002, M. Lopez Gil and J. Brimacombe et al[24] in 2006 and Anand Kuppusamy and Naheed Azhar et al[2] in 2010.

SUMMARY

This prospective randomized comparative study compared the classical digital insertion technique with gum elastic bougie guided laryngoscope aided Proseal laryngeal mask airway insertion technique in sixty anaesthetized spontaneously breathing female patients undergoing elective minor gynaecological surgeries.

The results of my study are as follows:

- First attempt success rate was 93.33% with gum elastic bougie guided technique and 83.33% with digital technique.
- Effective airway time was significantly longer for gum elastic bougie guided technique (36.17seconds) when compared to digital technique (25.47seconds)
- Incidence of failed insertion was not significantly different in both groups. The commonest presentation of failed insertion of Proseal laryngeal mask airway was negative suprasternal notch tap test.
- Oropharyngeal leak pressure was significantly higher for gum elastic bougie guided technique (31.27mm Hg) when compared to digital technique (23.57mm Hg)
- There was no statistically significant visible blood staining on Proseal laryngeal mask airway, gum elastic bougie and laryngoscope in both techniques.

- There was no statistically significant airway trauma during insertion of Proseal laryngeal mask airway in both techniques.

- Incidence of dysphagia was more with gum elastic bougie guided technique while sore throat was more frequent in digital insertion of Proseal laryngeal mask airway.

- There was no significant hemodynamic response to Proseal laryngeal mask airway insertion with gum elastic bougie guided and digital techniques.

CONCLUSION

The gum elastic bougie guided insertion of Proseal laryngeal mask airway is an excellent alternative to classical digital technique in adults with regard to number of attempts to successful placement, hemodynamic response to insertion, airway trauma during insertion and presence of visible blood staining. High oropharyngeal leak pressure associated with gum elastic bougie guided insertion makes it a more effective alternative to classical digital technique.

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INFORMATION TO PARTICIPANTS

Investigator :

Name of the Participant :

Title:

"A comparative study of gum elastic bougie guided insertion of Proseal laryngeal mask airway with digital technique in anaesthetised spontaneously breathing patients undergoing elective minor gynaecological surgeries"

You are invited to take part in this research study. We have got approval from the Institutional Ethics Committee. You are asked to participate because you satisfy the eligibility criteria. We want to compare the two methods of insertion of Proseal laryngeal mask airway.

What is the purpose of the research:

Proseal laryngeal mask airway is a modified form of laryngeal mask airway with improved ventilatory characteristics and protection against regurgitation and gastric insufflation. This study compares gum elastic bougie guided and digital technique for insertion of Proseal laryngeal mask airway in terms of ease of insertion, number of attempts to successful placement, effective airway time, hemodynamic response to insertion and postoperative airway morbidity.

The Study Design:

All the patients in the study will be divided into two groups randomly and will be premedicated. General anaesthesia will be induced with Inj. Fentanyl and Inj. Propofol. Proseal laryngeal mask airway is inserted in the first group using digital technique and in the

second group using gum elastic bougie guidance. The ease and number of attempts of insertion are noted. Pulse rate and blood pressure are recorded prior to insertion. BP, PR, SpO_2 and $ETCO_2$ are measured 1mnt, 3mnts, 5mnts and 10 minutes after insertion. Anaesthesia is maintained with oxygen, nitrous oxide and sevoflurane. At the end of the procedure anaesthetic agents will be discontinued allowing smooth recovery of consciousness. Proseal laryngeal mask airway will be removed after recovery criteria are adequately met. Any visible blood staining on Proseal laryngeal mask airway, laryngoscope and gum elastic bougie are noted down. Mouth, lips and tongue are inspected for evidence of trauma. Complications if any will be noted and treated. All results of this study will be kept confidentially.

Benefits:

This study will help us in deciding which method of Proseal laryngeal mask airway insertion is better.

Discomforts and risks:

Postoperative sore throat, hoarseness of voice and laryngospasm has been reported, but can be managed effectively.

Postoperative nausea and vomiting can be prevented by giving antiemetic.

This intervention has been shown to be well tolerated as shown by previous studies. And if you do not want to participate you will have the alternative of setting the standard treatment and your safety is our prime concern.

Time :

Date :

Place :

Signature / Thumb Impression of Patient :

Patient’s Name :

Signature of the Investigator :

Name of the Investigator ;

PATIENT CONSENT FORM

Study title:

"A comparative study of gum elastic bougie guided insertion of Proseal laryngeal mask airway with digital technique in anaesthetized spontaneously breathing patients undergoing elective minor gynaecological surgeries"

Study centre:

Department of Anaesthesiology

Institute of Obstetrics and Gynaecology

Madras Medical College and Rajiv Gandhi Govt.

General Hospital

Chennai

Participant's name: I.P.No:

Age: Sex:

I confirm that I have understood the purpose of the procedure for the above study. I have the opportunity to ask questions and all my questions and doubts have been answered to my satisfaction.

I have been explained about the pitfalls in the procedure. I have been explained about the safety, advantages and disadvantages of the technique.

I understand that my participation in the study is voluntary and that I am free to withdraw at anytime without giving any reason.

I understand that investigator, regulatory authorities and the ethics committee will not need my permission to look at my health records both in respect to current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I understand that my identity will not be revealed in any information released to the third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from the study.

Date: Signature / thumb impression of the patient:

Place: Patient's name:

Signature of the investigator:

Name of the investigator:

ஆராய்ச்சி தகவல் தாள்

ஆராய்ச்சி தலைப்பு

கருப்பை சம்பந்தமான நோய்க்கு சிறிய அறுவை சிகிச்சைகளில் முழு மயக்கத்தின் மூலம் இயல்பாக மூச்சு விடும்போது குரல்வளை சுவாச சாதனம் ProSeal LMA பயன்படுத்தும் Gum Elastic Bougie Guided Insertion மற்றும் Digital Insertion முறைகளை ஒப்பிடுதல்.

ஆராய்ச்சியாளரின் பெயர் :
பங்கேற்பாளர் பெயர் :

ஆராய்ச்சியின் நோக்கம்

முழு மயக்கம் கொடுத்து அறுவை சிகிச்சை செய்யும்பொழுது மூச்சு பெருங்குழலுள் குழாய் (Endotracheal Tube) மற்றும் குரல்வளை முகமூடி சுவாச சாதனம் (Supraglotic Airway Device) பயன்படுகிறது. இவை இரண்டில் குரல்வளை முகமூடி சுவாச சாதனம் பரவலாக சிறிய அறுவை சிகிச்சையில் பயன்படுத்தப்படுகிறது. இந்த ஆய்வில் குரல்வளை சுவாச சாதனமான ProSeal LMA பயன்படுத்தி இரண்டு விதமான Gum Elastic Bougie Guided Insertion மற்றும் Digital Insertion முறைகளில் ஒப்பிடப்படும்.

1. எளிய முறையில் உட்புகுத்துதல் தன்மை, எத்தனை முறை முயற்ச்சி செய்யப்படுகிறது,
   உட்புகுத்த எடுத்துக்கொள்ளும் நேரம் ஒப்பிடப்படுகிறது.
2. $ETCO_2$, SpO_2 இரத்த அழுத்தம், நாடித்துடிப்பு மாற்றம் ஒப்பிடுதல்.
3. பின்விளைவுகள், உபாதைகள் ஒப்பிடுதல்.

ஆய்வின் தன்மை

பங்குபெரும் நோயாளிகள் இரண்டு குழுக்களாக பிரிக்கப்படுவர்.
குழு-1 : Gum Elastic Bougie முறையில் PLMA வை பயன்படுத்துதல்.
குழு-2 : Digital முறையில் PLMA வை பயன்படுத்துதல்.

தானாக மூச்சு விடும் முழு மயக்கத்தின் போது மேலே கூறப்பட்ட மாற்றங்கள் ஒப்பிடப்படும்.

ஆய்வினால் ஏற்படும் நன்மைகள் :

இந்த ஆய்வின் மூலம் நாம் எந்த குரல்வளை முகமூடி சுவாச சாதனம் முழு மயக்கம் கொடுத்து தானாக மூச்சு விடும்பொழுது உயர்ந்தது என்பதை அறியலாம்.

மூச்சுக்குழலுக்குள் குழாய் சொருகுதல் (Intubation) மூலம் ஏற்படும் பக்க விளைவுகள் தவிர்க்கப்படும்.

உபாதைகள் :

தொண்டையில் லேசான கரகரப்பு , இருமல்,குரலில் சிறிது மாற்றம் , வாந்தி ஏற்படலாம். ஆனால் இவை அனைத்தும் உடனுக்குடன் கண்டுபிடித்து உரிய சிகிச்சை அளிக்கப்படும்.

நீங்கள் இந்த ஆய்வில் பங்குகொள்ள விருப்பப்படவில்லை என்றால் எப்போதும் உபயோகப்படுத்தப்படும் முறையில் மருந்து கொடுக்கப்படும் அல்லது முழு மயக்கம் கொடுக்கப்படும் . உங்கள் பாதுகாப்பே எங்களின் முக்கிய நோக்கம். இந்த ஆய்வின் மூலம் கிடைக்கும் அனைத்து தகவல்களும் பாதுகாப்பாக வைக்கப்படும்.

சாட்சியின் கையொப்பம்:

பெயர்:

நாள் :
இடம்:

பங்கேற்பாளர் கையொப்பம்
இடது கட்டைவிரல் ரேகை
பெயர்:

ஆய்வாளரின் பெயர்
ஆய்வாளரின் கையொப்பம்

ஆராய்ச்சி ஒப்புதல் படிவம்

ஆராய்ச்சி தலைப்பு

கருப்பை சம்பந்தமான நோய்க்கு சிறிய அறுவை சிகிச்சைகளில் முழு மயக்கத்தின் மூலம் இயல்பாக மூச்சு விடும்போது குரல்வளை சுவாச சாதனம் ProSeal LMA பயன்படுத்தும் Gum Elastic Bougie Guided Insertion மற்றும் Digital Insertion முறைகளை ஒப்பிடுதல்.

ஆராய்ச்சி நிலையம் : மயக்கவியல் துறை, அரசு மகப்பேறு மற்றும் குடும்பநல மருத்துவமனை, சென்னை- 600 008.

பங்கு பெறுபவரின் பெயர் :

பாலினம் :

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது . என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களைப் பெறவும் வாய்ப்பளிக்கப்பட்டது. ☐

நான் இவ்வாய்வில் தன்னிச்சையாகத்தான் பங்கேற்கிறேன் . எந்தகாரணத்தினாலோ எந்த கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகி கொள்ளலாம் என்றும் அறிந்து கொண்டேன். ☐

இந்த ஆய்வு சம்மந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்க்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன். ☐

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக்கொள்ளவும் அதை பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கின்றேன். ☐

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்கு கொடுக்கப்பட்ட அறிவுரைகளின்படி நடந்து கொள்வதுடன் இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்று உறுதியளிக்கிறேன். ☐

மேலும் இந்த ஆராய்ச்சியினால் ஏற்படும் நன்மைகளையும் சில பக்கவிளைவுகளையும் பற்றி தெளிவாக மருத்துவர் மூலம் தெரிந்துகொண்டேன். நான் என்னுடைய சுய நினைவுடனும் மற்றும் முழு சுதந்திரத்துடனும் இந்த மருத்துவ ஆராய்ச்சியில் என்னை சேர்த்துக்கொள்ள சம்மதம் தெரிவிக்கிறேன். ☐

நாள் :
இடம் :

கலந்து கொள்பவரின் கைரேகை
கையொப்பம்
பெயர்

ஆய்வாளரின் கையொப்பம் :
ஆய்வாளரின் பெயர் :

PROFORMA

A COMPARATIVE STUDY OF GUM ELASTIC BOUGIE GUIDED INSERTION OF PROSEAL LARYNGEAL MASK AIRWAY WITH DIGITAL TECHNIQUE

Name: Age: Sex:

IP No: Roll No:

Diagnosis:

Surgical procedure:

Pre-operative assessment:

History of co-morbid illness:

History of documented difficult airway:

History of any drug allergy:

Height: Weight: BMI:

CVS: RS:

Modified Mallampati Score: ASA-PS:

Technique used:

Digital/ gum elastic bougie guided:

Measures of study outcome:

- Number of attempts:
- Effective airway time:
- Failed attempts: Yes / No

- If yes,

Reasons for failed insertion	1st	2nd	3rd
1)Failed passage into pharynx			
2)Malposition a)Air leak - Oropharynx - Gastric - Drain tube b)Suprasternal notch tap test (+/-)			
3)Ineffective ventilation TV < 8ml/kg, ET CO_2> 45mmHg			

- Oropharyngeal leak pressure (mm Hg):

- Hemodynamic parameters:

	Heart rate	**Systolic BP**	**Diastolic BP**	**MAP**
Pre-insertion				
Post-insertion: 1minute				
3minutes				
5minutes				
10minutes				

- Visible blood staining:

Visible blood staining on	Yes	No
Laryngoscope		
PLMA		
GEB		

- Airway trauma:

Airway trauma	Yes	No
Tongue		
Lips		
Mouth		

- Post-operative airway morbidity:

Post-operative airway morbidity	Yes	No
Sore throat		
Dysphonia		
Dysphagia		

- Presence of other complications :

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013
Telephone No. 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr.Joona .P
Postgraduate M.D.(Anaesthesiology)
Madras Medical College
Chennai 600 003

Dear Dr.Joona. P,

The Institutional Ethics Committee has considered your request and approved your study titled **"A comparative study of Gum Elastic Bougie guided insertion of ProSeal Laryngeal Mask Airway with digital technique in anaesthetised spontaneously breathing patients undergoing elective minor gynaecological surgeries" No.03022015.**

The following members of Ethics Committee were present in the meeting held on 03.02.2015 conducted at Madras Medical College, Chennai-3.

1.	Dr.C.Rajendran, M.D.,	: Chairperson
2.	Dr.R.Vimala, M.D., Dean, MMC, Ch-3	: Deputy Chairperson
3.	Prof.B.Kalaiselvi, M.D., Vice-Principal, MMC, Ch-3	: Member Secretary
4.	Prof.R.Nandini, M.D., Inst.of Pharmacology, MMC	: Member
5.	Prof.P.Ragumani, M.S., Professor, Inst.of Surgery, MMC	: Member
6.	Prof.Md.Ali, M.D., D.M., Prof. & HOD of Medl.G.E., MMC	: Member
7.	Prof.K.Ramadevi, Director, Inst.of Biochemistry, MMC	: Member
8.	Prof.Saraswathy, M.D., Director, Pathology, MMC, Ch-3	: Member
9.	Prof.S.G.Sivachidambaram, M.D.,Director i/c Institute of Internal Medicine, MMC, Ch-3	: Member
10.	Thiru S.Rameshkumar	: Lay Person
11.	Thiru S.Govindasamy, B.A., B.L.,	: Lawyer
12.	Tmt.Arnold Saulina, M.A., MSW.,	: Social Scientist

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

4/2/15

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

Member Secretary, Ethics Committee

S No	NAME	I.P NUMBER	AGE	METHOD	EAT	ATTEMPTS	FAILED INSERTION						OLP	VISIBLE BLOOD STAINING
				D/B	{sec}		AL-OP	AL-G	AL-DT	FPP	SSN TT	IV	{mm Hg}	PLMA/GEB/LARYNGOSCPOE
1	Poongavanam	12706	46	D	27	1	-	-	-	-	+	-	24	nil
2	Nandhini	12709	41	D	14	1	-	-	-	-	+	-	23	nil
3	Eshwari	12747	45	D	11	1	-	-	-	-	+	-	26	nil
4	Mumtaj	12739	33	D	32	1	-	-	-	-	+	-	20	PLMA
5	Nagammal	12806	48	D	34	1	-	-	-	-	+	-	22	nil
6	Nagapushpa	12391	44	D	15	2	-	-	-	-	-	-	19	nil
7	Kanchana	12093	52	D	12	1	-	-	-	-	+	-	24	nil
8	Lalitha	13135	35	D	18	1	-	-	-	-	+	-	20	nil
9	Jyothi	13122	46	D	44	2	+	-	-	-	-	-	23	nil
10	Malarkodi	13111	45	D	28	1	-	-	-	-	+	-	27	PLMA
11	Sridevi	13124	36	D	22	1	-	-	-	-	+	-	24	nil
12	Hajabee	11080	28	D	16	1	-	-	-	-	+	-	28	nil
13	Lakshmi	13406	56	D	15	1	-	-	-	-	+	-	23	nil
14	Yasmin	13393	46	D	12	1	-	-	-	-	+	-	21	PLMA
15	Indra	12169	37	D	13	1	-	-	-	-	+	-	25	nil
16	Anjali	14072	49	D	24	1	-	-	-	-	+	-	19	nil
17	Dhanalakshmi	12236	42	D	56	3	+	+	+	-	-	-	28	nil
18	Shanthi	12968	39	D	32	1	-	-	-	-	+	-	27	nil
19	Selvi	12920	41	D	49	2	-	-	-	+	-	+	24	nil
20	Jagadeshwari	13138	33	D	24	1	-	-	-	-	+	-	22	nil
21	Nirmala	14599	47	D	22	1	-	-	-	-	+	-	24	nil
22	Vijaya	13267	54	D	28	1	-	-	-	-	+	-	20	PLMA
23	Ganga	14227	49	D	19	1	-	-	-	-	+	-	24	nil
24	Thenmozhi	14830	35	D	21	1	-	-	-	-	+	-	27	nil
25	Dhanam	14050	46	D	32	1	-	-	-	-	+	-	18	nil
26	Kamatchi	14935	43	D	51	2	-	-	-	+	-	+	24	nil
27	Saraswathi	15280	45	D	24	1	-	-	-	-	+	-	23	nil
28	Manjula	15097	48	D	19	1	-	-	-	-	+	-	28	nil
29	Thulasi	15422	30	D	22	1	-	-	-	-	+	-	26	PLMA
30	Lakshmi	15463	44	D	28	1	-	-	-	-	+	-	24	nil
31	Shanthi	14696	48	B	38	1	-	-	-	-	+	-	35	nil
32	Subbammal	14839	42	B	46	2	-	-	-	+	-	+	28	nil
33	Selvi	14641	36	B	32	1	-	-	-	-	+	-	32	nil
34	Eshwari	15643	49	B	28	1	-	-	-	-	+	-	26	nil
35	Lakshmi	15924	56	B	32	1	-	-	-	-	+	-	30	nil
36	Alamelu	11259	48	B	36	1	-	-	-	-	+	-	32	nil

37	Vijaya	16281	28	B	31	1	-	-	-	-	+	-	38	nil
38	Jayanthi	15824	44	B	34	1	-	-	-	-	+	-	39	PLMA
39	Rukmani	15770	41	B	36	1	-	-	-	-	+	-	34	nil
40	Rajeshwari	17196	39	B	39	1	-	-	-	-	+	-	35	nil
41	Venda	16391	48	B	48	1	-	-	-	-	+	-	28	PLMA
42	Murugammal	16390	41	B	26	1	-	-	-	-	+	-	23	nil
43	Renugadevi	16669	35	B	31	1	-	-	-	-	+	-	32	nil
44	Rajashwari	16665	46	B	38	1	-	-	-	-	+	-	28	nil
45	Annalakshmi	16024	52	B	36	1	-	-	-	-	+	-	30	nil
46	Rukmani	15793	38	B	34	1	-	-	-	-	+	-	32	nil
47	Ellammal	16028	42	B	39	1	-	-	-	-	+	-	36	nil
48	Pramila	17105	34	B	41	1	-	-	-	-	+	-	27	PLMA
49	Pushpa	17132	46	B	36	1	-	-	-	-	+	-	25	nil
50	Shanthi	17098	44	B	32	1	-	-	-	-	+	-	36	nil
51	Kala	17143	40	B	35	1	-	-	-	-	+	-	28	nil
52	Jayalakshmi	15530	42	B	37	1	-	-	-	-	+	-	32	GEB
53	Vijayalakshmi	17657	31	B	32	1	-	-	-	-	+	-	30	nil
54	Mallika	15642	44	B	31	1	-	-	-	-	+	-	24	nil
55	Nirmala	17763	36	B	37	1	-	-	-	-	+	-	29	nil
56	Saraswathi	14933	48	B	34	1	-	-	-	-	+	-	34	nil
57	Kumari	17912	47	B	59	2	+	+	+	-	+	-	38	PLMA
58	Selvi	17936	59	B	42	1	-	-	-	-	+	-	32	nil
59	Usha	16854	47	B	27	1	-	-	-	-	+	-	29	nil
60	Selvi	13121	45	B	38	1	-	-	-	-	+	-	36	nil

AIRWAY TRAUMA	AIRWAY MORBIDITY	HEMODYNAMICS																			
TONGUE/LIPS/MOUTH		HR[per minute}					SBP{mm Hg}					DBP{mm Hg}					MAP{mm Hg}				
		PRE	1	3	5	10	PRE	1	3	5	10	PRE	1	3	5	10	PRE	1	3	5	10
nil	nil	69	64	67	58	64	136	98	94	108	117	92	66	68	75	82	106	77	77	86	94
nil	nil	80	76	75	69	72	122	110	98	94	108	86	73	66	68	70	98	85	77	77	81
nil	nil	90	94	82	85	79	132	90	96	104	112	84	62	60	65	74	100	71	72	78	87
nil	nil	84	78	70	72	79	140	109	110	118	124	94	69	75	83	75	109	89	87	95	91
nil	nil	82	71	65	73	76	108	92	86	98	106	76	68	57	73	76	87	76	67	81	86
nil	nil	88	82	74	79	71	132	97	100	112	104	82	64	61	66	74	99	75	74	81	84
nil	nil	76	64	68	60	65	126	98	102	100	118	75	68	62	70	74	92	78	75	80	89
nil	nil	98	74	78	62	69	144	102	108	106	112	90	72	68	74	70	108	82	81	85	84
Tongue	Sore throat	102	84	80	75	86	128	92	98	92	109	83	76	70	73	78	98	81	79	79	88
nil	nil	62	74	76	69	66	112	98	106	102	108	76	70	74	65	70	88	79	85	77	83
nil	nil	83	89	74	78	72	110	90	87	98	106	72	64	69	62	66	85	73	75	74	79
nil	nil	74	62	69	65	70	108	92	94	104	98	78	62	70	65	68	88	72	78	78	78
nil	nil	68	62	70	67	64	146	124	109	122	128	90	72	78	82	85	109	89	88	95	99
nil	nil	62	58	54	59	53	133	118	106	112	120	80	68	74	72	66	98	85	85	85	84
nil	nil	64	71	66	72	68	128	108	96	106	110	72	66	69	63	70	91	80	78	77	83
nil	nil	74	70	66	72	68	122	90	94	104	116	66	62	58	60	64	85	71	70	75	81
nil	Sore throat	82	74	69	76	70	126	104	98	110	106	68	60	62	66	58	87	75	74	81	74
nil	nil	78	65	62	67	73	130	102	108	113	108	75	62	67	64	69	93	75	81	80	82
nil	nil	102	80	75	86	81	122	98	104	109	114	80	66	72	74	70	94	77	83	86	85
nil	nil	86	70	78	72	76	130	119	124	116	120	92	86	74	78	73	105	97	91	91	89
nil	nil	100	86	92	84	90	132	124	108	114	118	96	78	72	67	78	108	93	84	83	91
nil	Sore throat	76	64	69	72	66	122	100	108	115	112	78	62	67	71	65	93	75	81	86	81
nil	nil	78	66	62	67	73	110	92	98	100	104	72	60	62	58	64	85	71	74	72	77
nil	nil	102	90	84	92	88	120	108	112	110	106	70	65	71	64	68	87	79	85	79	81
nil	nil	98	84	88	82	87	132	115	106	122	110	75	64	68	62	65	94	81	81	82	80
nil	nil	90	82	74	80	75	126	112	108	104	114	80	70	72	76	70	95	84	84	85	85
nil	Sore throat	78	74	80	66	72	130	116	110	105	120	88	80	75	72	77	102	92	87	83	91
nil	nil	86	70	74	78	69	124	118	112	108	113	74	71	62	68	65	91	87	79	81	81
nil	nil	104	90	83	92	87	138	110	124	120	126	90	76	78	66	70	106	87	93	84	89
nil	nil	78	66	60	64	67	125	113	107	115	106	86	82	74	78	72	99	92	85	90	83
nil	nil	92	86	80	84	77	132	111	104	116	112	94	75	70	79	86	107	87	81	91	95
nil	nil	74	70	64	69	71	118	102	108	111	105	79	66	71	74	68	92	78	83	86	80
nil	nil	98	74	78	83	75	110	94	98	104	96	74	66	68	72	80	86	75	78	83	85
nil	nil	56	52	58	60	53	146	125	118	124	120	92	78	74	82	75	110	94	89	96	90
nil	nil	86	68	74	72	77	136	116	122	120	118	87	72	75	69	72	103	87	91	86	87
nil	Dysphagia	78	72	65	75	69	120	103	112	109	106	76	64	70	62	67	91	78	84	77	80

Lips	nil	108	92	86	94	89	138	117	110	122	115	98	75	73	79	76	111	89	85	93	89
nil	nil	92	86	81	89	84	117	102	95	107	108	82	76	69	72	74	94	85	78	84	85
nil	nil	86	78	72	77	73	113	107	98	102	110	70	58	62	68	64	84	74	74	79	79
nil	nil	94	82	88	79	85	144	128	122	117	120	95	82	76	78	84	111	97	91	91	96
nil	nil	100	86	92	82	85	126	106	114	112	114	78	62	66	60	64	94	77	82	77	81
nil	Dysphagia	95	84	78	72	76	110	94	90	98	92	66	54	58	62	56	81	67	69	74	68
nil	nil	82	67	74	78	69	118	103	109	105	108	72	64	58	62	60	87	77	75	76	76
Mouth	nil	76	63	69	74	70	130	115	109	116	112	86	74	68	70	78	101	88	82	85	89
nil	nil	94	86	82	79	84	122	107	113	103	106	78	66	72	65	68	93	80	86	78	81
nil	Dysphagia	106	82	94	86	90	108	98	92	90	96	64	56	54	52	58	79	70	67	65	71
nil	nil	86	67	62	74	69	132	124	116	122	118	94	76	72	75	69	107	92	87	91	85
nil	nil	72	64	69	62	68	124	110	104	113	104	72	66	62	69	65	89	81	76	84	78
nil	nil	92	85	79	73	78	115	102	108	102	108	74	64	67	60	66	88	77	81	74	80
nil	nl	68	72	70	62	66	106	98	92	104	96	68	56	54	62	54	81	70	67	76	68
nil	nil	78	64	72	68	75	123	114	103	112	106	84	76	66	74	64	97	89	78	87	78
nil	Dysphagia	94	78	72	66	76	134	116	107	114	110	90	68	64	70	66	105	84	78	85	81
nil	nil	82	74	67	75	70	116	103	102	110	104	76	64	56	58	52	89	77	71	75	69
nil	nil	103	90	82	86	89	122	104	112	103	108	74	66	64	56	67	90	79	80	72	81
Lips	nil	98	81	72	77	83	138	116	122	108	114	88	74	68	62	65	105	88	86	77	81
nil	nil	82	76	71	79	75	106	100	94	89	97	62	65	59	53	58	77	77	71	65	71
nil	nil	86	74	69	72	77	112	98	103	94	100	74	56	64	58	62	87	70	77	70	75
nil	Dysphagia	97	89	83	74	85	135	124	118	122	114	86	90	75	72	78	102	101	89	89	90
nil	nil	72	64	58	66	68	114	98	106	92	98	76	66	72	58	62	89	77	83	69	74
nil	nil	88	69	75	72	78	128	107	112	104	115	74	58	66	64	70	92	74	81	77	85